Practitioner's Docket No. 870-003.137 JC17 Rec'd PCT/PTO 28 JUN 2001

CHAPTER II 09/869514

Preliminary Classification: 604
Proposed Class: 134
Subclass:

NOTE: "All applicants are requested to include a preliminary classification on newly filed patent applications. The preliminary classification, preferably class and subclass designations, should be identified in the upper right-hand corner of the letter of transmittal accompanying the application papers, for example 'Proposed Class 2, subclass 129.'" M.P.E.P., § 601, 7th ed.

TRANSMITTAL LETTER TO THE UNITED STATES ELECTED OFFICE (EO/US) (ENTRY INTO U.S. NATIONAL PHASE UNDER CHAPTER II)

PCT/EP00/00194	13 January 2000	14 January 1999
INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED

INJECTION DEVICE
TITLE OF INVENTION

Herbert BECHTOLD, Gerhard HAMBRECHT, Ulf POLZIN and Jurgen HORL
APPLICANT(S)

Box PCT
Assistant Commissioner for Patents
Washington D.C. 20231
ATTENTION: EO/US

CERTIFICATION UNDER 37 C.F.R. §§ 1.8(a) and 1.10*
(When using Express Mail, the Express Mail label number is mandatory; Express Mail certification is optional.)

I hereby certify that, on the date shown below, this correspondence is being:

MAILING

☒ deposited with the United States Postal Service in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231

37 C.F.R. § 1.8(a)

☐ with sufficient postage as first class mail.

37 C.F.R. § 1.10 *

☒ as "Express Mail Post Office to Addressee"
Mailing Label No. EL628641411US **(mandatory)**

TRANSMISSION

☐ facsimile transmitted to the Patent and Trademark Office, (703) _____-_____

Date: June 28, 2001

Judith Schick
Signature

Judith Schick
(type or print name of person certifying)

** Only the date of filing (§ 1.6) will be the date used in a patent term adjustment calculation, although the date on any certificate of mailing or transmission under § 1.8 continues to be taken into account in determining timeliness. See § 1.703(f). Consider "Express Mail Post Office to Addressee" (§ 1.10) or facsimile transmission (§ 1.6(d)) for the reply to be accorded the earliest possible filing date for patent term adjustment calculations.*

I. Applicant herewith submits to the United States Elected Office (EO/US) the following items under 35 U.S.C. 371:

a. ☒ This express request to immediately begin national examination procedures (35 U.S.C. 371(f)).

b. ☒ The U.S. National Fee (35 U.S.C. 371(c)(1)) and other fees (37 CFR 1.492) as indicated below:

09/869514

JC18 Rec'd PCT/PTO 28 JUN 2001

Docket No. 870-003.157

2. Fees

CLAIMS FEE	(1) FOR	(2) NUMBER FILED	(3) NUMBER EXTRA	(4) RATE	(5) CALCULATIONS
☐*	TOTAL CLAIMS	26 -20=	6	18.00 × ~~$22.00~~ =	$ 108.00
	INDEPENDENT CLAIMS	9 -3=	6	80.00 × ~~$78.00~~ =	480.00
	MULTIPLE DEPENDENT CLAIM(S) (if applicable)		0	+ $250.00	
BASIC FEE**	☐ U.S. PTO WAS INTERNATIONAL PRELIMINARY EXAMINATION AUTHORITY Where an International preliminary examination fee as set forth in § 1.482 has been paid on the international application to the U.S. PTO: ☐ and the international preliminary examination report states that the criteria of novelty, inventive step (non-obviousness) and industrial activity, as defined in PCT Article 33(1) to (4) have been satisfied for all the claims presented in the application entering the national stage (37 CFR 1.492(a)(4)) ..... $94.00 ☐ and the above requirements are not met (37 CFR 1.492(a)(1)) ..... $680.00 ☒ U.S. PTO WAS NOT INTERNATIONAL PRELIMINARY EXAMINATION AUTHORITY Where no international preliminary examination fee as set forth in § 1.482 has been paid to the U.S. PTO, and payment of an international search fee as set forth in § 1.445(a)(2) to the U.S. PTO: ☐ has been paid (37 CFR 1.492(a)(2)) ..... $750.00 ☐ has not been paid (37 CFR 1.492(a)(3)) ..... $1,010.00 ☒ where a search report on the international application has been prepared by the European Patent Office or the Japanese Patent Office (37 CFR 1.492(a)(5)) ..... ~~$880.00~~ 860.00				860.00
				Total of above Calculations	= 1448.00
SMALL ENTITY	Reduction by 1/2 for filing by small entity, if applicable. Affidavit must be filed also. (note 37 CFR 1.9, 1.27, 1.28)				-
				Subtotal	
				Total National Fee	$ 1448.00
	Fee for recording the enclosed assignment document $40.00 (37 CFR 1.21(h)). (See Item 13 below). See attached "ASSIGNMENT COVER SHEET".				0.00
TOTAL				Total Fees enclosed	$ 1448.00

*See attached Preliminary Amendment Reducing the Number of Claims.

i. ☒ A check in the amount of 1448.00 to cover the above fees is enclosed.

ii. ☐ Please charge Account No. _____ in the amount of $ _____. A duplicate copy of this sheet is enclosed.

***WARNING:** *"To avoid abandonment of the application the applicant shall furnish to the United States Patent and Trademark Office not later than the expiration of 30 months from the priority date: * * * (2) the basic national fee (see § 1.492(a)). The 30-month time limit may not be extended." 37 CFR § 1.495(b).*

WARNING: *If the translation of the international application and/or the oath or declaration have not been submitted by the applicant within thirty (30) months from the priority date, such requirements may be met within a time period set by the Office. 37 CFR § 1.495(b)(2). The payment of the surcharge set forth in § 1.492(e) is required as a condition for accepting the oath or declaration later than thirty (30) months after the priority date. The payment of the processing fee set forth in § 1.492(f) is required for acceptance of an English translation later than thirty (30) months after the priority date. Failure to comply with these requirements will result in abandonment of the application. The provisions of § 1.136 apply to the period which is set. Notice of January 3, 1993, 1147 O.G. 29 to 40.*

3. ☒ A copy of the International application as filed (35 U.S.C. 371(c)(2)):

NOTE: Section 1.495 (b) was amended to require that the basic national fee and a copy of the international application must be filed with the Office by 30 months from the priority date to avoid abandonment. "The International Bureau normally provides the copy of the international application to the Office in accordance with PCT Article 20. At the same time, the International Bureau notifies applicant of the communication to the Office. In accordance with PCT Rule 47.1, that notice shall be accepted by all designated offices as conclusive evidence that the communication has duly taken place. Thus, if the applicant desires to enter the national stage, the applicant normally need only check to be sure the notice from the International Bureau has been received and then pay the basic national fee by 30 months from the priority date." Notice of January 7, 1993, 1147 O.G. 29 to 40, at 35-36. See item 14c below.

a. ☒ is transmitted herewith.

b. ☐ is not required, as the application was filed with the United States Receiving Office.

c. ☐ has been transmitted

i. ☐ by the International Bureau.
Date of mailing of the application (from form PCT/1B/308): _____.

ii. ☐ by applicant on (date) _____.

4. ☒ A translation of the International application into the English language (35 U.S.C. 371(c)(2)):

a. ☒ is transmitted herewith.

b. ☐ is not required as the application was filed in English.

c. ☐ was previously transmitted by applicant on (*date*) _____.

d. ☐ will follow.

5. ☐ Amendments to the claims of the International application under PCT Article 19 (35 U.S.C. 371(c)(3)):

NOTE: *The Notice of January 7, 1993 points out that 37 CFR § 1.495(a) was amended to clarify the existing and continuing practice that PCT Article 19 amendments must be submitted by 30 months from the priority date and this deadline may not be extended. The Notice further advises that: "The failure to do so will not result in loss of the subject matter of the PCT Article 19 amendments. Applicant may submit that subject matter in a preliminary amendment filed under section 1.121. In many cases, filing an amendment under section 1.121 is preferable since grammatical or idiomatic errors may be corrected." 1147 O.G. 29-40, at 36.*

a. ☐ are transmitted herewith.

b. ☐ have been transmitted

i. ☐ by the International Bureau.
Date of mailing of the amendment (from form PCT/1B/308): _____.

ii. ☐ by applicant on (date) _____.

c. ☒ have not been transmitted as

i. ☒ applicant chose not to make amendments under PCT Article 19.
Date of mailing of Search Report (from form PCT/ISA/210.): _____.

ii. ☐ the time limit for the submission of amendments has not yet expired. The amendments or a statement that amendments have not been made will be transmitted before the expiration of the time limit under PCT Rule 46.1.

6. ☐ A translation of the amendments to the claims under PCT Article 19 (38 U.S.C. 371(c)(3)):

a. ☐ is transmitted herewith.

b. ☐ is not required as the amendments were made in the English language.

c. ☐ has not been transmitted for reasons indicated at point 5c above.

7. ☒ A copy of the international examination report (PCT/IPEA/409)

☒ is transmitted herewith.

☐ is not required as the application was filed with the United States Receiving Office.

8. ☒ Annex(es) to the international preliminary examination report

a. ☒ is/are transmitted herewith.

b. ☐ is/are not required as the application was filed with the United States Receiving Office.

9. ☒ A translation of the annexes to the international preliminary examination report

a. ☒ is transmitted herewith.

b. ☐ is not required as the annexes are in the English language.

10. ☒ An oath or declaration of the inventor (35 U.S.C. 371(c)(4)) complying with 35 U.S.C. 115

    a. ☐ was previously submitted by applicant on (date) _____.

    b. ☐ is submitted herewith, and such oath or declaration

        i. ☐ is attached to the application.

        ii. ☐ identifies the application and any amendments under PCT Article 19 that were transmitted as stated in points 3b or 3c and 5b; and states that they were reviewed by the inventor as required by 37 CFR 1.70.

        iii. ☒ will follow.

II. Other document(s) or information included:

11. ☒ An International Search Report (PCT/ISA/210) or Declaration under PCT Article 17(2)(a):

    a. ☒ is transmitted herewith.

    b. ☒ has been transmitted by the International Bureau. Date of mailing (from form PCT/IB/308): 20 JUNE 2000

    c. ☐ is not required, as the application was searched by the United States International Searching Authority.

    d. ☐ will be transmitted promptly upon request.

    e. ☐ has been submitted by applicant on (date) _____.

12. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98:

    a. ☒ is transmitted herewith.

        Also transmitted herewith is/are:

        ☒ Form PTO-1449.

        ☒ Copies of citations listed.

    b. ☐ will be transmitted within THREE MONTHS of the date of submission of requirements under 35 U.S.C. 371(c).

    c. ☐ was previously submitted by applicant on (date) _____.

13. ☐ An assignment document is transmitted herewith for recording.

    A separate ☐ "COVER SHEET FOR ASSIGNMENT (DOCUMENT) ACCOMPANYING NEW PATENT APPLICATION" or ☐ FORM PTO 1595 is also attached.

_____

_____

_____

14. ☐ Additional documents:
    a. ☐ Copy of request (PCT/RO/101)
    b. ☒ International Publication No. WO 00/41754
        i. ☒ Specification, claims and drawing
        ii. ☐ Front page only
    c. ☒ Preliminary amendment (37 CFR § 1.121)
    d. ☐ Other

15. ☒ The above checked items are being transmitted
    a. ☒ before 30 months from any claimed priority date.
    b. ☐ after 30 months.

16. ☐ Certain requirements under 35 U.S.C. 371 were previously submitted by the applicant on _____, namely:

AUTHORIZATION TO CHARGE ADDITIONAL FEES

WARNING: *Accurately count claims, especially multiple dependant claims, to avoid unexpected high charges if extra claims are authorized.*

☒ The Commissioner is hereby authorized to charge the following additional fees that may be required by this paper and during the entire pendency of this application to Account No. 23-0442.

☒ 37 CFR 1.492(a)(1), (2), (3), and (4) (filing fees)

WARNING: *Because failure to pay the national fee within 30 months without extension (37 CFR § 1.495(b)(2)) results in abandonment of the application, it would be best to always check the above box.*

☐ 37 CFR 1.492(b), (c) and (d) (presentation of extra claims)

NOTE: Because additional fees for excess or multiple dependent claims not paid on filing or on later presentation must only be paid or these claims cancelled by amendment prior to the expiration of the time period set for response by the PTO in any notice of fee deficiency (37 CFR 1.492(d)), it might be best not to authorize the PTO to charge additional claim fees, except possible when dealing with amendments after final action.

☒ 37 CFR 1.17 (application processing fees) JC18 Rec'd PCT/PTO 28 JUN 2001

WARNING: *While 37 CFR 1.17(a), (b), (c) and (d) deal with extensions of time under § 1.136(a), this authorization should be made only with the knowledge that: "Submission of the appropriate extension fee under 37 CFR 1.136(a) is to no avail unless a request or petition for extension is filed." Notice of November 5, 1985 (1060 O.G. 27).*

☐ 37 CFR 1.18 (issue fee at or before mailing of Notice of Allowance, pursuant to 37 CFR 1.311(b))

NOTE: Where an authorization to charge the issue fee to a deposit account has been filed before the mailing of a Notice of Allowance, the issue fee will be automatically charged to the deposit account at the time of mailing the notice of allowance. 37 CFR 1.311(b).

NOTE: 37 CFR 1.28(b) requires "Notification of any change in loss of entitlement to small entity status must be filed in the application . . . prior to paying, or at the time of paying . . . issue fee." From the wording of 37 CFR 1.28(b): (a) notification of change of status must be made even if the fee is paid as "other than a small entity" and (b) no notification is required if the change is to another small entity.

☐ 37 CFR 1.492(e) and (f) (surcharge fees for filing the declaration and/or filing an English translation of an International Application later than 30 months after the priority date).

Milton M. Oliver

SIGNATURE OF ATTORNEY

Reg. No.: 28,333

Milton M. Oliver

(type or print name of attorney)

Tel. No.: (203) 261-1234

Ware, Fressola, Van Der Sluys & Adolphson LLP

P.O. Address Building Five, Bradford Green
755 Main Street, P.O. Box 224

USPTO Customer No. 004955

Monroe, CT 06468

IN THE U.S. PATENT & TRADEMARK OFFICE

Applicants: BECHTOLD et al.

Serial #: 09/_____ = § 371 of PCT/EP00/00194

Filed: 28 JUN. 2001 (HEREWITH)

Title: INJECTION DEVICE

Examiner: Not yet assigned ART UNIT: 3760

PRELIMINARY AMENDMENT TO PCT APPLICATION

Assistant Commissioner for Patents 28 JUN. 2001
Washington, D.C. 20231

Sir:
Prior to counting the claims,

please amend the application as follows:

IN THE SPECIFICATION:

Please replace specification pages 1-6

with REPLACEMENT SHEETS per the attachment.

A version marked up to show the changes made is also enclosed.

"Express Mail" Mailing Label No. **EL 628 641 411 US**
Date of Deposit: **JUNE 28, 2001**

I hereby certify that this document is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. 1.10 on the date indicated above and is addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231.

Judith Schick

Judith Schick

IN THE CLAIMS:

1. (Amended) An injection device comprising

a container (80) for reception of a cartridge (52) which contains an injection fluid (53) and on whose proximal end an injection needle (76) can be mounted,

a barrel (50, 48, 46, 36) in which said container (80) is displaceable between a proximal end position and a distal end position,

a plunger (108), arranged in the barrel and serving to expel injection fluid (53) out of the cartridge (52), which plunger during an injection is guided in a guide member (124) axially displaceably but nonrotatably relative to the barrel, and which has an external thread (159) that is guided in an internal thread (152) of a setting member (151) serving to set the injection dose, and

a frictionally engaging coupling (162, 250), in the manner of a slip coupling, between the container (80) and the plunger (108), for transferring at least a portion of an axial movement of the plunger (108) to the container (80).

2.(Amended) The injection device according to claim 1, wherein the setting member (151) has associated with it a spring (172) for biasing the setting member (151) in the proximal direction, and the setting member (151) is displaceable against the force of said spring (172) into a distal position (FIG. 3) and is releasably latchable there.

3. (Amended) The injection device according to claim 2, wherein

the setting member (151) is displaceable from the proximal end of the barrel into a distal position (FIG. 3) and is releasably latchable there.

4.(Retyped) The injection device according to claim 3, wherein

for cocking the spring (172), a cocking member (56) is provided which can be joined, from the proximal end of the injection device (30), to a thread (60) of the injection device, in order to displace the container (80), using a distal end region of the cocking member (56), in the proximal direction.

5.(Amended) The injection device according to claim 1, wherein

the setting member (151) is, in at least one distal position (FIG. 2), rotatable relative to the barrel of the injection device in order to make possible an axial displacement of the plunger (108) relative to the barrel for the purpose of setting an injection dose (Y).

6. (Amended) An injection device comprising

a container (80) for reception of a cartridge (52) which contains an injection fluid (53) and on whose proximal end an injection needle (76) can be mounted,

a barrel (50, 48, 46, 36) in which said container (80) is displaceable between a proximal end position and a distal end position,

a plunger (108), arranged in the barrel and serving to expel injection fluid out of the cartridge (52), which is guided in a guide member (124) axially displaceably but nonrotatably relative to the guide member, and which has an external thread (159) that is guided in an internal thread (152) of a setting member (151),

a cocking spring (172) biasing the setting member (151) in the proximal direction and, during an injection operation, causes displacement thereof into a proximal end position, and against the force of which the setting member (151) can be displaced into a distal end position and releasably latched there,

a first coupling arrangement (K4), for nonrotatable but axially displaceable coupling of the setting member (151) to the barrel, which is deactivated in the distal end position of the setting member (151),

and a second coupling arrangement (K5), for nonrotatable but axially displaceable coupling of the guide member (124) to the barrel, which is activated in the entire region between the distal and proximal end positions of the guide member (124).

7. (Retyped) The injection device according to claim 6, comprising

a connection (282), provided between guide member (124) and setting member (151), that joins said parts to one another rotatably but substantially axially nondisplaceably.

8. (Amended) The injection device according to claim 6, wherein

both the guide member (124) and the setting member (151) have external splines (274 and 222, respectively), and said external spline sets have associated therewith internal splines (134) in the barrel (36), into which said external spline sets (222, 274) can engage, individually or together, by means of a longitudinal displacement of guide member (124) and setting member (151) occurring relative to the barrel (36).

9. (Retyped) The injection device according to claim 8, wherein

the setting member (151) is equipped with a latching member (64), by means of which the setting member (151) can be releasably latched in a predefined axial position relative to the barrel (36) in which its external splines (222) are not in engagement with the internal splines (134) in the barrel (36).

10.(Amended) The injection device according to claim 8, wherein the setting member is equipped with a latching member (64), by means of which the guide member (124) can be releasably latched in a predefined axial position relative to the barrel (36) in which its external splines (274) are in engagement with the internal splines (134) in the barrel (36).

11.(Amended) The injection device according to claim 9, wherein the setting member (151) is rotatable relative to the latching member (64) provided on it.

PLEASE CANCEL, WITHOUT PREJUDICE, CLAIMS 12-35.

36. (Amended) An injection device comprising

a barrel (50, 48, 46, 36),

a plunger (108), arranged in said barrel and serving to expel injection fluid out of a container (52) containing an injection fluid,

which plunger is guided in a guide member (124) axially displaceably but nonrotatably relative to the guide member,

and which has an external thread (159) that is guided in an internal thread (152) of a setting member (151),

a cocking spring (172) which biases the setting member (151) in the proximal direction,

a latch (38, 64), provided between barrel and setting member (151), for releasably latching the setting member (124) in a distal position (FIG. 23) in which the cocking spring (172) is cocked,

the cocking spring (172), after disengagement of the latch (38, 64), displacing the setting member (151) a defined distance (FIG. 25: L) out of said distal position (FIG. 23) into a proximal end position (FIG. 25),

external splines (222), provided on the setting member (151), for longitudinal guidance of the setting member (151) in barrel-mounted internal splines (134) substantially complementary to said splines (222), and

external splines (274), provided on the guide member (124), for longitudinal guidance of the guide member (124) in the barrel-mounted internal splines (134).

37. The injection device according to claim 36, wherein

the length of the barrel-mounted internal splines (134) corresponds at least to the aforesaid predefined distance (L).

PLEASE CANCEL, WITHOUT PREJUDICE, CLAIMS 38-43.

44. (Amended) An injection device comprising

a container (80) for reception of a cartridge (52) which contains an injection fluid (53) and on whose proximal end an injection needle (76) can be mounted,

a barrel (50, 48, 46, 36) in which said container (80) is displaceable between a proximal end position and a distal position,

a plunger (108), arranged in the barrel and serving to expel injection fluid (53) out of the cartridge (52), which plunger during an injection is guided in a guide member (124) axially displaceably but nonrotatably relative to the barrel, and which has an external thread (159) that is guided in an internal thread (152) of a setting member (151) serving to set the injection dose,

and an apparatus for modifying an axial spacing (Y) in the region between the setting member (151) and the container (80) for purposes of dose setting.

45. (Amended) The injection device according to claim 44, wherein during an injection, the axial spacing (Y) increased upon dose setting is reduced to zero.

46. (Amended) An injection device comprising

a container (80) for reception of a cartridge (52) which contains an injection fluid (53) and on whose proximal end an injection needle (76) can be mounted,

a plunger (108), arranged in the barrel and serving to expel injection fluid (53) out of the cartridge (52), which plunger has an external thread (159) that is guided in an internal thread (152) of a setting member (151) serving to set the injection dose, and which is guided axially displaceably in a guide member (124),

a drive connection (232, 234, 266, 268, 270, 272) which is provided between the guide member (124) and the container (80) and which comprises an apparatus (118, 242; 232, 234) that limits, in at least one rotation direction, the torque transferable from the container (80) to the guide member (124).

47. The injection device according to claim 46, wherein the apparatus for limiting the torque comprises a slip coupling (232, 234).

PLEASE CANCEL, WITHOUT PREJUDICE, CLAIMS 48-50.

51. (Amended) An injection device comprising

a barrel (36, 46, 48) wherein a dose-setting apparatus (FIG. 15), for setting a fluid quantity to be injected, is arranged displaceably between a distal end position (FIG. 3) and a proximal end position (FIG. 25),

said dose-setting apparatus having associated therewith a setting member (32) for dose setting, and the dose-setting apparatus being, at least in its proximal end position (FIG. 25), out of engagement with said setting member (32).

52. (Amended) An injection device according to claim 51, wherein a dose-setting apparatus (FIG. 15), for setting a fluid quantity to be injected, is arranged displaceably between a distal end position (FIG. 3) and a proximal end position (FIG. 25),

said dose-setting apparatus having associated with it a setting member (32) for dose setting, and the dose-setting apparatus (FIG. 15) being, at least in its distal end position (FIG. 3), out of engagement with said setting member (32).

PLEASE CANCEL, WITHOUT PREJUDICE, CLAIMS 53-67.

68. (Amended) An injection device comprising

an indicating apparatus for the injection dose that is set, in a generally cylindrical automatic injection device,

comprising a scale (69') having,

in a first row (71), a first series of indicating digits and, in a second row (73), a second series of indicating digits,

and a double magnifier (42), serving to indicate the dose, of which a first lens (70) is associated with the first row (71), and a second lens (72) is associated with the second row (73), of indicating digits.

PLEASE CANCEL, WITHOUT PREJUDICE, CLAIMS 69-70.

71. (Amended) An injection device comprising

a housing (50, 48, 46, 36) with a container (80), arranged in said housing, for reception of a cartridge (52) which contains an injection fluid (53) and on whose proximal end an injection needle (76) can be mounted,

a plunger (108), arranged in the housing and serving to expel injection fluid out of the cartridge (52), which is guided in a guide member (124) axially displaceably but nonrotatably relative to the guide member,

and which has an external thread (159) that is guided in an internal thread (152) of a setting member (151) provided for dose setting,

a first coupling arrangement (K4) for nonrotatable but axially displaceable coupling of the setting member (151) to the housing, said coupling arrangement (K4) being deactivated during dose setting,

a second coupling arrangement (K5) for nonrotatable but axially displaceable coupling of the guide member (124) to the housing,

and an apparatus (50) for activating the first coupling arrangement (K4) and for disabling the second coupling arrangement (K5), in order to make the guide member (124) rotatable relative to the housing and the setting member (151) nonrotatable relative to the housing, and to make possible an axial movement of the plunger (108) by rotation of the guide member (124).

72. (Amended) The injection device according to claim 71, wherein there is provided, between guide member (124) and setting member (151), a connection (278, 282) that joins said two parts to one another rotatably but substantially axially nondisplaceably.

PLEASE CANCEL, WITHOUT PREJUDICE, CLAIMS 73-104.

105. (Amended) An injection device comprising

a container (80) for reception of a cartridge (52) which contains an injection fluid (53) said cartridge having a proximal end adapted for mounting thereon of an injection needle (76),

a housing (50, 48, 46, 36) in which said container (80) is displaceable between a proximal and a distal position,

a plunger (108), arranged in the housing and serving to expel injection fluid (53) out of the cartridge (52), which has an external thread (159),

a setting member (151) having an internal thread (152) adapted to engage said external thread (159) of said plunger, said setting member serving to set the injection dose,

and said setting member being guided axially displaceably in a guide member (124), and

a drive connection (232, 234, 266, 268, 270, 272) which is provided between the guide member (124) and the container (80) and which comprises an apparatus (118, 242; 232, 234) that limits, in at least one rotation direction, a torque transferable from the container (80) to the guide member (124),

in order to make possible, by the transfer of a limited torque from the container (80) to the guide member (124) after a cartridge replacement, a displacement of the plunger (108) in the proximal direction into contact against a piston (106) provided in the cartridge (52).

106. (Retyped) The injection device according to claim 105, wherein the apparatus for limiting the torque comprises a slip coupling (232, 234).

PLEASE CANCEL, WITHOUT PREJUDICE, CLAIMS 107-108.

REMARKS

Applicants have made the foregoing amendments to place the PCT application text in customary US format, so that all the claims can be considered on their merits. All multiple dependent claims have been cancelled.

The specification has been amended to insert customary headings and to replace references to the content of the claims. Most of the foreign documents (or their English equivalents) mentioned in the specification are included in the Information Disclosure Statement filed herewith. If the Patent Office notes any remaining informalities which would prevent or hinder examination on the merits, a telephone call to Applicants' counsel is requested.

Respectfully submitted,

Milton Oliver

Milton Oliver, Reg. No. 28,333
WARE, FRESSOLA, VAN DER SLUYS
& ADOLPHSON, LLP
PO BOX 224
MONROE, CT 06468
Tel. (203) 261-1234
Fax (203) 261-5676

Att. Docket No. 870-003-137

CLAIMS TEXT MARKED TO SHOW CHANGES MADE

1. (Amended) An injection device comprising

a container (80) for reception of a cartridge (52) which contains an injection fluid (53) and on whose proximal end an injection needle (76) can be mounted,

[comprising] a barrel (50, 48, 46, 36) in which said container (80) is displaceable between a proximal end position and a distal end position,

[comprising] a plunger (108), arranged in the barrel and serving to expel injection fluid (53) out of the cartridge (52), which plunger during an injection is guided in a guide member (124) axially displaceably but nonrotatably relative to the barrel, and which has an external thread (159) that is guided in an internal thread (152) of a setting member (151) serving to set the injection dose,

and [comprising] a frictionally engaging coupling (162, 250), in the manner of a slip coupling, between the container (80) and the plunger (108), for transferring at least a portion of an axial movement of the plunger (108) to the container (80).

2. (Amended) The injection device according to claim 1, [in which] <u>wherein</u> the setting member (151) has associated with it a spring (172) for biasing the setting member (151) in the proximal direction, and the setting member (151) [can be displaced] <u>is displaceable</u> against the force of said spring (172) into a distal position (FIG. 3) and [releasably latched] <u>is releasably latchable</u> there.

3.(Amended) The injection device according to claim 2, wherein

the setting member (151) [can be displaced] is displaceable from the proximal end of the barrel into a distal position (FIG. 3) and [releasably latched] is releasably latchable there.

4.(Retyped) The injection device according to claim 3, wherein

for cocking the spring (172), a cocking member (56) is provided which can be joined, from the proximal end of the injection device (30), to a thread (60) of the injection device, in order to displace the container (80), using a distal end region of the cocking member (56), in the proximal direction.

5.(Amended) The injection device according to claim 1, [one or more of the foregoing claims,] wherein

the setting member (151) is, in at least one distal position (FIG. 2), rotatable relative to the barrel of the injection device in order to make possible an axial displacement of the plunger (108) relative to the barrel for the purpose of setting an injection dose (Y).

6. (Amended) An injection device comprising

a container (80) for reception of a cartridge (52) which contains an injection fluid (53) and on whose proximal end an injection needle (76) can be mounted,

[comprising] a barrel (50, 48, 46, 36) in which said container (80) is displaceable between a proximal end position and a distal end position,

[comprising] a plunger (108), arranged in the barrel and serving to expel injection fluid out of the cartridge (52), which is guided in a guide member (124) axially displaceably but nonrotatably relative to the guide member, and which has an external thread (159) that is guided in an internal thread (152) of a setting member (151),

[comprising] a cocking spring (172) biasing the setting member (151) in the proximal direction and, during an injection operation, causes displacement thereof into a proximal end position, and against the force of which the setting member (151) can be displaced into a distal end position and releasably latched there,

[comprising] a first coupling arrangement (K4), for nonrotatable but axially displaceable coupling of the setting member (151) to the barrel, which is deactivated in the distal end position of the setting member (151),

and [comprising] a second coupling arrangement (K5), for nonrotatable but axially displaceable coupling of the guide member (124) to the barrel, which is activated in the entire region between the distal and proximal end positions of the guide member (124).

7. (Retyped) The injection device according to claim 6, comprising

a connection (282), provided between guide member (124) and

setting member (151), that joins said parts to one another rotatably but substantially axially nondisplaceably.

8. (Amended) The injection device according to claim 6[or 7,] wherein

both the guide member (124) and the setting member (151) have external splines (274 and 222, respectively), and said external spline sets have associated therewith internal splines (134) in the barrel (36), into which said external spline sets (222, 274) can engage, individually or together, by means of a longitudinal displacement of guide member (124) and setting member (151) occurring relative to the barrel (36).

9.(Retyped) The injection device according to claim 8, wherein

the setting member (151) is equipped with a latching member (64), by means of which the setting member (151) can be releasably latched in a predefined axial position relative to the barrel (36) in which its external splines (222) are not in engagement with the internal splines (134) in the barrel (36).

10.(Amended) The injection device according to claim 8 [or 9], wherein the setting member is equipped with a latching member (64), by means of which the guide member (124) can be releasably latched in a predefined axial position relative to the barrel (36) in which its external splines (274) are in engagement with the internal splines (134) in the barrel (36).

11.(Amended) The injection device according to claim 9[or 10,] wherein the setting member (151) is rotatable relative

to the latching member (64) provided on it.

PLEASE CANCEL, WITHOUT PREJUDICE, CLAIMS 12-35.

36. (Amended) An injection device comprising

a barrel (50, 48, 46, 36),

[comprising] a plunger (108), arranged in said barrel and serving to expel injection fluid out of a container (52) containing an injection fluid,

which plunger is guided in a guide member (124) axially displaceably but nonrotatably relative to the guide member,

and which has an external thread (159) that is guided in an internal thread (152) of a setting member (151),

[comprising] a cocking spring (172) which biases the setting member (151) in the proximal direction,

[comprising] a latch (38, 64), provided between barrel and setting member (151), for releasably latching the setting member (124) in a distal position (FIG. 23) in which the cocking spring (172) is cocked,

the cocking spring (172), after disengagement of the latch (38, 64), displacing the setting member (151) a defined distance (FIG. 25: L) out of said distal position (FIG. 23) into a proximal end position (FIG. 25),

[comprising] external splines (222), provided on the setting member (151), for longitudinal guidance of the setting member (151) in barrel-mounted internal splines (134) substantially complementary to said splines (222),

and [comprising] external splines (274), provided on the guide member (124), for longitudinal guidance of the guide member (124) in the barrel-mounted internal splines (134).

37. The injection device according to claim 36, wherein the length of the barrel-mounted internal splines (134)

corresponds at least to the aforesaid predefined distance (L).

PLEASE CANCEL, WITHOUT PREJUDICE, CLAIMS 38-43.

44. (Amended) An injection device comprising

a container (80) for reception of a cartridge (52) which contains an injection fluid (53) and on whose proximal end an injection needle (76) can be mounted,

[comprising] a barrel (50, 48, 46, 36) in which said container (80) is displaceable between a proximal end position and a distal position,

[comprising] a plunger (108), arranged in the barrel and serving to expel injection fluid (53) out of the cartridge (52), which plunger during an injection is guided in a guide member (124) axially displaceably but nonrotatably relative to the barrel, and which has an external thread (159) that is guided in an internal thread (152) of a setting member (151) serving to set the injection dose,

and [comprising] an apparatus for modifying an axial spacing (Y) in the region between the setting member (151) and the container (80) for purposes of dose setting.

45. (Amended) The injection device according to claim 44, wherein during an injection, the axial spacing (Y) increased upon dose setting is [reduced, and in particular is] reduced to zero.

46. (Amended) An injection device comprising

a container (80) for reception of a cartridge (52) which contains an injection fluid (53) and on whose proximal end an injection needle (76) can be mounted,

[comprising] a plunger (108), arranged in the barrel and serving to expel injection fluid (53) out of the cartridge (52), which plunger has an external thread (159) that is guided in an

internal thread (152) of a setting member (151) serving to set the injection dose,

and which is guided axially displaceably in a guide member (124),

[comprising] a drive connection (232, 234, 266, 268, 270, 272) which is provided between the guide member (124) and the container (80) and which comprises an apparatus (118, 242; 232, 234) that limits, in at least one rotation direction, the torque transferable from the container (80) to the guide member (124).

47. The injection device according to claim 46, wherein the apparatus for limiting the torque comprises a slip coupling (232, 234).

PLEASE CANCEL, WITHOUT PREJUDICE, CLAIMS 48-50.

51. (Amended) An injection device comprising

a barrel (36, 46, 48) wherein a dose-setting apparatus (FIG. 15), for setting a fluid quantity to be injected, is arranged displaceably between a distal end position (FIG. 3) and a proximal end position (FIG. 25),

said dose-setting apparatus having associated therewith a setting member (32) for dose setting,

and the dose-setting apparatus being, at least in its proximal end position (FIG. 25), out of engagement with said setting member (32).

52. (Amended) An injection device [, in particular] according to claim 51, wherein a dose-setting apparatus (FIG. 15), for setting a fluid quantity to be injected, is arranged displaceably between a distal end position (FIG. 3) and a proximal end position (FIG. 25),

said dose-setting apparatus having associated with it a

setting member (32) for dose setting,

and the dose-setting apparatus (FIG. 15) being, at least in its distal end position (FIG. 3), out of engagement with said setting member (32).

PLEASE CANCEL, WITHOUT PREJUDICE, CLAIMS 53-67.

68. (Amended) An injection device comprising

an indicating apparatus for the injection dose that is set, [in particular according to one or more of the foregoing claims,] in a generally cylindrical automatic injection device,

comprising a scale (69') [which comprises] having, in a first row (71), a first series of indicating digits and, in a second row (73), a second series of indicating digits,

and [comprising] a double magnifier (42), serving to indicate the dose, of which [the one magnifier] a first lens (70) is associated with the first row (71), and [the other magnifier] a second lens (72) is associated with the second row (73), of indicating digits.

PLEASE CANCEL, WITHOUT PREJUDICE, CLAIMS 69-70.

71. (Amended) An injection device comprising

a housing (50, 48, 46, 36) with a container (80), arranged in said housing, for reception of a cartridge (52) which contains an injection fluid (53) and on whose proximal end an injection needle (76) can be mounted,

[comprising] a plunger (108), arranged in the housing and serving to expel injection fluid out of the cartridge (52), which is guided in a guide member (124) axially displaceably but nonrotatably relative to the guide member,

and which has an external thread (159) that is guided in an internal thread (152) of a setting member (151) provided for dose

setting,

[comprising] a first coupling arrangement (K4) for nonrotatable but axially displaceable coupling of the setting member (151) to the housing, said coupling arrangement (K4) being deactivated during dose setting,

[comprising] a second coupling arrangement (K5) for nonrotatable but axially displaceable coupling of the guide member (124) to the housing,

and [comprising] an apparatus (50) for activating the first coupling arrangement (K4) and for disabling the second coupling arrangement (K5), in order to make the guide member (124) rotatable relative to the housing and the setting member (151) nonrotatable relative to the housing, and to make possible an axial movement of the plunger (108) by rotation of the guide member (124).

72. (Amended) The injection device according to claim 71, wherein there is provided, between guide member (124) and setting member (151), a connection (278, 282) that joins said two parts to one another rotatably but substantially axially nondisplaceably.

PLEASE CANCEL, WITHOUT PREJUDICE, CLAIMS 73-104.

105. (Amended) An injection device comprising

a container (80) for reception of a cartridge (52) which contains an injection fluid (53) [and on whose] <u>said cartridge having a</u> proximal end <u>adapted for mounting thereon of</u> an injection needle (76) [can be mounted],

[comprising] a housing (50, 48, 46, 36) in which said container (80) is displaceable between a proximal and a distal position,

[comprising] a plunger (108), arranged in the housing and

serving to expel injection fluid (53) out of the cartridge (52), which has an external thread (159),

[that is guided in an internal thread (152) of]

a setting member (151) having an internal thread (152) adapted to engage said external thread (159 of said plunger, said setting member serving to set the injection dose,

and [which is] said setting member being guided axially displaceably in a guide member (124), and [comprising]

a drive connection (232, 234, 266, 268, 270, 272) which is provided between the guide member (124) and the container (80) and which comprises an apparatus (118, 242; 232, 234) that limits, in at least one rotation direction, a torque transferable from the container (80) to the guide member (124),

in order to make possible, by the transfer of a limited torque from the container (80) to the guide member (124) after a cartridge replacement, a displacement of the plunger (108) in the proximal direction into contact against a piston (106) provided in the cartridge (52).

106. (Retyped) The injection device according to claim 105, wherein the apparatus for limiting the torque comprises a slip coupling (232, 234).

PLEASE CANCEL, WITHOUT PREJUDICE, CLAIMS 107-108.

SPECIFICATION – SUBSTITUTE SHEETS 1-6A

INJECTION DEVICE

FIELD OF THE INVENTION

The invention relates to an injection device comprising a container for reception of a cartridge which contains an injection fluid and on whose proximal end an injection needle can be mounted.

BACKGROUND

An injection device of this kind is known from DE 42 23 958-A1 and corresponding U.S. Patent 5,480,387, BECHTOLD & GABRIEL. The injection device depicted and described therein operates very reliably and precisely, but is less suitable for the use of large cartridges comprising larger quantities of injection fluid.

SUMMARY OF THE INVENTION

It is therefore an object of the invention to make a new injection device available.

This object is achieved in one manner by using a special coupling to transfer at least a portion of axial movement of a plunger to the container. As a result of the frictionally engaging connection in the manner of a slip coupling, during an injection the container first follows the axial movement of the plunger until the container has reached its proximal end position. The frictionally engaging connection between plunger and container then releases, and allows an expulsion of the preset dose of injection fluid by means of the plunger, which then moves independently of the container.

The stated object is achieved in a different manner by using a first coupling which is deactivated in a distal position of a setting member, and a second coupling which is activated in an entire axial region between the distal and proximal end positions of a guide member. An injection device of this kind has a simple configuration and operates very reliably and

comfortably for the patient.

The stated object is achieved in a different manner by using a cocking spring to displace a setting member and by guiding axial movement of the components using barrel-mounted splines. An injection device of this kind combines high precision with simple operation and compact design.

Other ways of achieving the stated object are involve dose setting by modifying an axial spacing Y between a setting member and a container, and by using a drive connection between a guide member and the container which limits transfer of torque between these components. The principle of modifying axial spacing Y is highly suitable for injection devices with an automatic injection sequence, and the principle of limiting transfer of torque is particularly "foolproof" when a used cartridge needs to be replaced with a new one.

The stated object is achieved in another manner by allowing a dose-setting apparatus to move axially, and having the apparatus, in its proximal end position, be out of engagement. Because the setting member is not in engagement with the dose-setting apparatus when the latter is in its proximal end position, the setting member can there conveniently be reset into its zero position, either manually or preferably automatically, for example by means of a return spring.

In this context, it is particularly advantageous for the dose-setting apparatus to be out of engagement in its distal end position. The result is that a dose setting is not possible when the dose-setting apparatus is in the distal end position, but is possible only after leaving that end position. This is important because in this fashion, improper operation due to "playing around" with the setting member can be prevented. This counteracts improper dose setting, and thus constitutes a valuable safety feature.

BRIEF FIGURE DESCRIPTION

Further details and advantageous developments of the invention are evident from the exemplary embodiments described hereinafter and depicted in the drawings, which are in no way to be understood as a limitation of the invention.

In the drawings:

FIG. 1 is a three-dimensional depiction of an injection device according to the present invention, as an overview depiction;

FIG. 2 is a side view of the injection device of FIG. 1 in which cocking cap 56 is unscrewed and depicted next to the device;

FIG. 2A schematically depicts a development of a scale usable in an injection device according to the present invention;

FIG. 3 is a depiction analogous to FIG. 1, a proximal segment of the barrel being depicted in section;

FIG. 4 is a depiction of the injection device after an injection, the proximal part being depicted in longitudinal section;

FIG. 5 is an exploded, three-dimensional depiction of components of the proximal part of the injection device;

FIG. 6 is an exploded, three-dimensional depiction which shows various components of the middle part of a device according to the present invention;

FIG. 7 is an exploded, three-dimensional depiction analogous to FIG. 6, which also shows parts of a device according to the present invention;

FIG. 8 is a three-dimensional, enlarged, depiction of a preferred form of a plunger that can be used in the present invention;

FIG. 9 is an exploded, three-dimensional depiction of components of the distal part of the injection device, in a depiction analogous to FIGS. 6 and 7 but at a larger scale;

FIG. 10 is a longitudinal section through a part which forms, inter alia, a clip that serves as trigger for an injection;

FIG. 11 is a longitudinal section through the setting knob of an injection device according to the present invention;

FIG. 12 is a side view of a component of a setting sleeve that is used for dose setting in an injection device according to the present invention;

FIG. 13 is a greatly enlarged depiction of the parts of a setting sleeve which is used for dose setting in an injection device according to the present invention;

FIG. 14 is a three-dimensional depiction of a front and a rear adapter part, in a depiction enlarged as compared to FIG. 6;

FIG. 15 is a longitudinal section through various parts that are arranged in the barrel of the injection device, to explain their functional interaction;

FIG. 16 is a depiction of an injection device according to the present invention in which cocking cap 56 is screwed on but the patient has forgotten to insert an injection needle; the device cannot be cocked;

FIG. 17 is an enlarged depiction of detail XVII of FIG. 16;

FIG. 18 is a depiction analogous to FIG. 15, emphasizing various couplings K1 through K10 which, in their functional interaction, contribute to the mode of operation of the injection device according to the present invention;

FIG. 19 is a longitudinal section through an injection device according to the present invention in its cocked position, i.e. in the position shown in FIGS. 1 and 3;

FIG. 20 is a section viewed along line XX-XX of FIG. 19;

FIG. 21 is a section viewed along line XXI-XXI of FIG. 19;

FIG. 22 shows a longitudinal section through an injection device according to the present invention, in its cocked position and after unscrewing the cocking cap; this position corresponds

to the position of FIG. 2;

FIG. 23 is a longitudinal section analogous to FIG. 22, except that an injection dose has been set;

FIG. 24 is a longitudinal section through an injection device according to the present invention during the first phase of an injection (needle inserted, but before expulsion of injection fluid);

FIG. 25 is a longitudinal section analogous to FIG. 24 but during the second phase of an injection (expulsion of injection fluid after insertion of the needle);

FIG. 26 is a longitudinal section depicting the beginning of a cartridge replacement;

FIG. 27 is a depiction which, continuing from FIG. 26, shows a further phase of cartridge replacement;

FIG. 28 is a depiction showing a phase of cartridge replacement subsequent to FIG. 27;

FIG. 29 is an enlarged depiction of detail XXIX of FIG. 28 which shows the latching of plunger 108 in its distal end position;

FIG. 30 is a schematic depiction showing how a used cartridge 52 is removed from cartridge holder 80;

FIG. 31 shows how a new cartridge is introduced into cartridge holder 80;

FIG. 32 shows how the cartridge holder just loaded (as shown in FIG. 31) is screwed onto the injection device;

FIG. 33 shows the phase subsequent to FIG. 32, i.e. the screwing on of the proximal barrel part and the operations occurring in that context;

FIG. 34 is a depiction of a variant in which, as compared to FIG. 1, a plurality of round holes 54A are used as the viewing window;

FIG. 35 is a plan view, viewed in the direction of arrow XXXV, of FIG. 34 but at a scale enlarged relative to FIG. 34;

FIG. 36 is a schematic depiction of splines 220 of setting sleeve 151 and of the interaction between those splines and a latching member 184 during dose setting prior to an injection;

FIG. 37 is a three-dimensional, exploded depiction of parts that play a role in cartridge replacement; and

FIGS. 38 through 40 provide a synoptic depiction to explain the manner of operation of couplings K4 and K5 in various operating states of an injection device according to the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS:

In the description below, the terms "proximal" and "distal" are used in the manner usual in medicine:

"Proximal" = the end facing toward the patient, i.e. in FIG. 3 the lower end of the injection device comprising the needle.

"Distal" = the end remote from the patient, i.e. the upper end in FIGS. 1 and 2.

FIG. 1 depicts, in three-dimensional and schematized form, an injection device 30 according to the present invention. The latter has at its distal end a setting knob 32 that, by rotation in the direction of an arrow 34, makes possible a dose setting if the device is in its position as shown in FIG. 2. (In the position as shown in FIG. 1, dose setting is not activated.) Knob 32 is arranged rotatably in a tubular distal barrel part 36 in which an elongated latch opening 38 is present and on which a resilient clip 40 is mounted. Located in clip 40 is a magnifier 42 for reading off the dose that is set. Clip 40 has a radially inwardly projecting protrusion 44 that serves to trigger an injection and is located opposite elongated latch opening 38.

Adjoining distal barrel part 36 in the proximal direction is an annular part 46 that is immovably joined to barrel part 36. This is followed, in the proximal direction, by a middle barrel part 48. Adjoining this in the proximal direction is a proximal barrel part 50 which receives a cartridge 52 comprising a fluid

53 to be injected (FIG. 4) and is equipped with at least one viewing window 54 through which the fill level of cartridge 52 can be observed.

Advantageously, as shown in FIG. 34, a plurality of small orifices 54A is used as the viewing window. This has the advantage that the patient's fingers cannot reach through window 54 and thereby slow down the motion of cartridge 52 during injection, but that the fill level of cartridge 52 can be very easily observed visually.

VERSION MARKED TO SHOW CHANGES

INJECTION DEVICE

FIELD OF THE INVENTION

The invention concerns an injection device comprising a container for reception of a cartridge which contains an injection fluid and on whose proximal end an injection needle can be mounted.

BACKGROUND

An injection device of this kind is known from DE 42 23 958 A1. and USP.... The injection device depicted and described therein operates very reliably and precisely, but is less suitable for the use of large cartridges comprising larger quantities of injection fluid.

SUMMARY OF THE INVENTION

It is therefore an object of the invention to make a new injection device available.

This object is achieved in one manner by [the subject matter of Claim 1.] INSERT PARAPHRASE As a result of the frictionally engaging connection in the manner of a slip coupling, during an injection the container first follows the axial movement of the plunger until the container has reached its proximal end position. The frictionally engaging connection between plunger and container then releases, and allows an expulsion of the preset dose of injection fluid by means of the plunger, which then moves independently of the container.

The stated object is achieved in a different manner by [the subject matter of Claim 6.] INSERT PARAPHRASE An injection device of this kind has a simple configuration and operates very reliably and comfortably for the patient.

The stated object is achieved in a different manner by [the subject matter of Claim 36.] INSERT PARAPHRASE An injection device of this kind combines high precision with simple operation and compact design.

Other ways of achieving the stated object are evident from [the subject matters of Claims 44 and 46.] The principle of [Claim 44] is highly suitable for injection devices with an automatic injection sequence, and the principle [recited in Claim 46] INSERT PARAPHRASE is particularly "foolproof" when a used cartridge needs to be replaced with a new one.

The stated object is achieved in another manner by [the subject matter of Claim 51.] INSERT PARAPHRASE Because the setting member is not in engagement with the dose-setting apparatus when the latter is in its proximal end position, the setting member can there conveniently be reset into its zero position, either manually or preferably automatically, for example by means of a return spring.

In this context, it is particularly advantageous to [proceed in accordance with Claim 52.] INSERT PARAPHRASE The result is that a dose setting is not possible when the dose-setting apparatus is in the distal end position, but is possible only after leaving that end position. This is important because in this fashion, improper operation due to "playing around" with the setting member can be prevented. This counteracts improper dose setting, and thus constitutes a valuable safety feature.

BRIEF FIGURE DESCRIPTION

Further details and advantageous developments of the invention are evident from the exemplary embodiments described hereinafter and depicted in the drawings - which are in no way to be understood as a limitation of the invention [- and from the dependent claims.]

In the drawings:

FIG. 1 is a three-dimensional depiction of an injection device according to the present invention, as an overview depiction;

FIG. 2 is a side view of the injection device of FIG. 1 in which cocking cap 56 is unscrewed and depicted next to the device;

FIG. 2A schematically depicts a development of a scale usable in an injection device according to the present invention;

FIG. 3 is a depiction analogous to FIG. 1, a proximal segment of the barrel being depicted in section;

FIG. 4 is a depiction of the injection device after an injection, the proximal part being depicted in longitudinal section;

FIG. 5 is an exploded, three-dimensional depiction of components of the proximal part of the injection device;

FIG. 6 is an exploded, three-dimensional depiction which shows various components of the middle part of a device according to the present invention;

FIG. 7 is an exploded, three-dimensional depiction analogous to FIG. 6, which also shows parts of a device according to the present invention;

FIG. 8 is a three-dimensional, enlarged, depiction of a preferred form of a plunger that can be used in the present invention;

FIG. 9 is an exploded, three-dimensional depiction of components of the distal part of the injection device, in a depiction analogous to FIGS. 6 and 7 but at a larger scale;

FIG. 10 shows a longitudinal section through a part which forms, inter alia, a clip that serves as trigger for an injection;

FIG. 11 shows a longitudinal section through the setting knob of an injection device according to the present invention;

FIG. 12 is a side view of a component of a setting sleeve that is used for dose setting in an injection device according to the present invention;

FIG. 13 is a greatly enlarged depiction of the parts of a setting sleeve which is used for dose setting in an injection device according to the present invention;

FIG. 14 is a three-dimensional depiction of a front and a rear adapter part, in a depiction enlarged as compared to FIG. 6;

FIG. 15 shows a longitudinal section through various parts that are arranged in the barrel of the injection device, to explain their functional interaction;

FIG. 16 is a depiction of an injection device according to the present invention in which cocking cap 56 is screwed on but the patient has forgotten to insert an injection needle; the device cannot be cocked;

FIG. 17 is an enlarged depiction of detail XVII of FIG. 16;

FIG. 18 is a depiction analogous to FIG. 15, emphasizing various couplings K1 through K10 which, in their functional interaction, contribute to the mode of operation of the injection device according to the present invention;

FIG. 19 shows a longitudinal section through an injection device according to the present invention in its cocked position, i.e. in the position shown in FIGS. 1 and 3;

FIG. 20 shows a section viewed along line XX-XX of FIG. 19;

FIG. 21 shows a section viewed along line XXI-XXI of FIG. 19;

FIG. 22 shows a longitudinal section through an injection device according to the present invention, in its cocked position and after unscrewing the cocking cap; this position corresponds to the position of FIG. 2;

FIG. 23 shows a longitudinal section analogous to FIG. 22, except that an injection dose has been set;

FIG. 24 shows a longitudinal section through an injection device according to the present invention during the first phase of an injection (needle inserted, but before expulsion of injection fluid);

FIG. 25 shows a longitudinal section analogous to FIG. 24 but during the second phase of an injection (expulsion of injection fluid after insertion of the needle);

FIG. 26 shows a longitudinal section depicting the beginning of a cartridge replacement;

FIG. 27 is a depiction which, continuing from FIG. 26, shows a further phase of cartridge replacement;

FIG. 28 is a depiction showing a phase of cartridge replacement subsequent to FIG. 27;

FIG. 29 is an enlarged depiction of detail XXIX of FIG. 28 which shows the latching of plunger 108 in its distal end position;

FIG. 30 is a schematic depiction showing how a used cartridge 52 is removed from cartridge holder 80;

FIG. 31 is a depiction showing how a new cartridge is introduced into cartridge holder 80;

FIG. 32 is a depiction showing how the cartridge holder just loaded (as shown in FIG. 31) is screwed onto the injection device;

FIG. 33 is a depiction showing the phase subsequent to FIG. 32, i.e. the screwing on of the proximal barrel part and the operations occurring in that context;

FIG. 34 is a depiction of a variant in which, as compared to FIG. 1, a plurality of round holes 54A are used as the viewing window;

FIG. 35 is a plan view, viewed in the direction of arrow XXXV, of FIG. 34 but at a scale enlarged relative to FIG. 34;

FIG. 36 is a schematic depiction of splines 220 of setting sleeve 151 and of the interaction between those splines and a latching member 184 during dose setting prior to an injection;

FIG. 37 is a three-dimensional, exploded depiction of parts that play a role in cartridge replacement; and

FIGS. 38 through 40 provide a synoptic depiction to explain the manner of operation of couplings K4 and K5 in various operating states of an injection device according to the invention.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

In the description below, the terms "proximal" and "distal" are used in the manner usual in medicine:

"Proximal" = the end facing toward the patient, i.e. in FIG. 3 the lower end of the injection device comprising the needle.

"Distal" = the end remote from the patient, i.e. the upper end in FIGS. 1 and 2.

FIG. 1 depicts, in three-dimensional and schematized form, an injection device 30 according to the present invention. The latter has at its distal end a setting knob 32 that, by rotation in the direction of an arrow 34, makes possible a dose setting if the device is in its position as shown in FIG. 2. (In the position as shown in FIG. 1, dose setting is not activated.) Knob 32 is arranged rotatably in a tubular distal barrel part 36 in which an elongated latch opening 38 is present and on which a resilient clip 40 is mounted. Located in clip 40 is a magnifier 42 for reading off the dose that is set. Clip 40 has a radially inwardly projecting protrusion 44 that serves to trigger an injection and is located opposite elongated latch opening 38.

Adjoining distal barrel part 36 in the proximal direction is an annular part 46 that is immovably joined to barrel part 36. This is followed, in the proximal direction, by a middle barrel part 48. Adjoining this in the proximal direction is a proximal barrel part 50 which receives a cartridge 52 comprising a fluid 53 to be injected (FIG. 4) and is equipped with at least one viewing window 54 through which the fill level of cartridge 52 can be observed.

Advantageously, as shown in FIG. 34, a plurality of small orifices 54A is used as the viewing window. This has the advantage that the patient's fingers cannot reach through window 54 and thereby slow down the motion of cartridge 52 during injection, but that the fill level of cartridge 52 can be very easily observed visually.

INJECTION DEVICE

The invention concerns an injection device comprising a container for reception of a cartridge which contains an injection fluid and on whose proximal end an injection needle can be mounted.

An injection device of this kind is known from DE 42 23 958 A1. The injection device depicted and described therein operates very reliably and precisely, but is less suitable for the use of large cartridges comprising larger quantities of injection fluid.

It is therefore an object of the invention to make a new injection device available.

This object is achieved in one manner by the subject matter of Claim 1. As a result of the frictionally engaging connection in the manner of a slip coupling, during an injection the container first follows the axial movement of the plunger until the container has reached its proximal end position. The frictionally engaging connection between plunger and container then releases, and allows an expulsion of the preset dose of injection fluid by means of the plunger, which then moves independently of the container.

The stated object is achieved in a different manner by the subject matter of Claim 6. An injection device of this kind has a simple configuration and operates very reliably and comfortably for the patient.

The stated object is achieved in a different manner by the subject matter of Claim 36. An injection device of this kind combines high precision with simple operation and compact design.

Other ways of achieving the stated object are evident from the subject matters of Claims 44 and 46. The principle of Claim 44 is highly suitable for injection devices with an automatic injection sequence, and the principle recited in Claim 46 is particularly "foolproof" when a used cartridge needs to be replaced with a new one.

The stated object is achieved in another manner by the subject matter of Claim 51.

Because the setting member is not in engagement with the dose-setting apparatus when the latter is in its proximal end position, the setting member can there conveniently be reset into its zero position, either manually or preferably automatically, for example by means of a return spring.

In this context, it is particularly advantageous to proceed in accordance with Claim 52.

The result is that a dose setting is not possible when the dose-setting apparatus is in the distal end position, but is possible only after leaving that end position. This is important because in this fashion, improper operation due to "playing around" with the setting member can be prevented. This counteracts improper dose setting, and thus constitutes a valuable safety feature.

Further details and advantageous developments of the invention are evident from the exemplary embodiments described hereinafter and depicted in the drawings - which are in no way to be understood as a limitation of the invention - and from the dependent claims.

In the drawings:

FIG. 1 is a three-dimensional depiction of an injection device according to the present invention, as an overview depiction;

FIG. 2 is a side view of the injection device of FIG. 1 in which cocking cap 56 is unscrewed and depicted next to the device;

FIG. 2A schematically depicts a development of a scale usable in an injection device according to the present invention;

FIG. 3 is a depiction analogous to FIG. 1, a proximal segment of the barrel being depicted in section;

FIG. 4 is a depiction of the injection device after an injection, the proximal part being depicted in longitudinal section;

FIG. 5 is an exploded, three-dimensional depiction of components of the proximal part of the injection device;

FIG. 6 is an exploded, three-dimensional depiction which shows various components of the middle part of a device according to the present invention;

FIG. 7 is an exploded, three-dimensional depiction analogous to FIG. 6, which also shows parts of a device according to the present invention;

FIG. 8 is a three-dimensional, enlarged, depiction of a preferred form of a plunger that can be used in the present invention;

FIG. 9 is an exploded, three-dimensional depiction of components of the distal part of the injection device, in a depiction analogous to FIGS. 6 and 7 but at a larger scale;

FIG. 10 shows a longitudinal section through a part which forms, inter alia, a clip that serves as trigger for an injection;

FIG. 11 shows a longitudinal section through the setting knob of an injection device according to the present invention;

FIG. 12 is a side view of a component of a setting sleeve that is used for dose setting in an injection device according to the present invention;

FIG. 13 is a greatly enlarged depiction of the parts of a setting sleeve which is used for dose setting in an injection device according to the present invention;

FIG. 14 is a three-dimensional depiction of a front and a rear adapter part, in a depiction enlarged as compared to FIG. 6;

FIG. 15 shows a longitudinal section through various parts that are arranged in the barrel of the injection device, to explain their functional interaction;

FIG. 16 is a depiction of an injection device according to the present invention in which cocking cap 56 is screwed on but the patient has forgotten to insert an injection needle; the device cannot be cocked;

FIG. 17 is an enlarged depiction of detail XVII of FIG. 16;

FIG. 18 is a depiction analogous to FIG. 15, emphasizing various couplings K1 through K10 which, in their functional interaction, contribute to the mode of operation of the injection device according to the present invention;

FIG. 19 shows a longitudinal section through an injection device according to the present invention in its cocked position, i.e. in the position shown in FIGS. 1 and 3;

FIG. 20 shows a section viewed along line XX-XX of FIG. 19;

FIG. 21 shows a section viewed along line XXI-XXI of FIG. 19;

FIG. 22 shows a longitudinal section through an injection device according to the present invention, in its cocked position and after unscrewing the cocking cap; this position corresponds to the position of FIG. 2;

FIG. 23 shows a longitudinal section analogous to FIG. 22, except that an injection dose has been set;

FIG. 24 shows a longitudinal section through an injection device according to the present invention during the first phase of an injection (needle inserted, but before expulsion of injection fluid);

FIG. 25 shows a longitudinal section analogous to FIG. 24 but during the second phase of an injection (expulsion of injection fluid after insertion of the needle);

FIG. 26 shows a longitudinal section depicting the beginning of a cartridge replacement;

FIG. 27 is a depiction which, continuing from FIG. 26, shows a further phase of cartridge replacement;

FIG. 28 is a depiction showing a phase of cartridge replacement subsequent to FIG. 27;

FIG. 29 is an enlarged depiction of detail XXIX of FIG. 28 which shows the latching of plunger 108 in its distal end position;

FIG. 30 is a schematic depiction showing how a used cartridge 52 is removed from cartridge holder 80;

FIG. 31 is a depiction showing how a new cartridge is introduced into cartridge holder 80;

FIG. 32 is a depiction showing how the cartridge holder just loaded (as shown in FIG. 31) is screwed onto the injection device;

FIG. 33 is a depiction showing the phase subsequent to FIG. 32, i.e. the screwing on of the proximal barrel part and the operations occurring in that context;

FIG. 34 is a depiction of a variant in which, as compared to FIG. 1, a plurality of round holes 54A are used as the viewing window;

FIG. 35 is a plan view, viewed in the direction of arrow XXXV, of FIG. 34 but at a scale enlarged relative to FIG. 34;

FIG. 36 is a schematic depiction of splines 220 of setting sleeve 151 and of the interaction between those splines and a latching member 184 during dose setting prior to an injection;

FIG. 37 is a three-dimensional, exploded depiction of parts that play a role in cartridge replacement; and

FIGS. 38 through 40 provide a synoptic depiction to explain the manner of operation of couplings K4 and K5 in various operating states of an injection device according to the invention.

In the description below, the terms "proximal" and "distal" are used in the manner usual in medicine:

"Proximal" = the end facing toward the patient, i.e. in FIG. 3 the lower end of the injection device comprising the needle.

"Distal" = the end remote from the patient, i.e. the upper end in FIGS. 1 and 2.

FIG. 1 depicts, in three-dimensional and schematized form, an injection device 30 according to the present invention. The latter has at its distal end a setting knob 32 that, by rotation in the direction of an arrow 34, makes possible a dose setting if the device is in its position as shown in FIG. 2. (In the position as shown in FIG. 1, dose setting is not activated.) Knob 32 is arranged rotatably in a tubular distal barrel part 36 in which an elongated latch opening 38 is present and on which a resilient clip 40 is mounted. Located in clip 40 is a magnifier 42 for reading off the dose that is set. Clip 40 has a radially inwardly projecting protrusion 44 that serves to trigger an injection and is located opposite elongated latch opening 38.

Adjoining distal barrel part 36 in the proximal direction is an annular part 46 that is immovably joined to barrel part 36. This is followed, in the proximal direction, by a middle barrel part 48. Adjoining this in the proximal direction is a proximal barrel part 50 which receives a cartridge 52 comprising a fluid 53 to be injected (FIG. 4) and is equipped with at least one viewing window 54 through which the fill level of cartridge 52 can be observed.

Advantageously, as shown in FIG. 34, a plurality of small orifices 54A is used as the viewing window. This has the advantage that the patient's fingers cannot reach through window 54 and thereby slow down the motion of cartridge 52 during injection, but that the fill level of cartridge 52 can be very easily observed visually.

Located at the proximal end of injection device 30, for cocking, is a cocking cap 56 that is screwed with its external thread 58 into a corresponding internal thread 60 (FIG. 2) of proximal barrel part 50, in order to cock the injection device prior to an injection. As described later with reference to FIGS. 16 and 17, cocking of injection device 30 is possible only if a needle 76 is installed. In the position as shown in FIG. 1, injection device 30 is therefore cocked, since a needle 76 is installed and cocking cap 56 has been screwed all the way into proximal barrel part 50. In this context, a resilient latching peg 64 is located at the distal end of elongated latch opening 38 (cf. FIG. 3). In this position setting knob 32 is "in neutral," i.e. it can be rotated in the direction of arrow 34 (FIG. 1) without setting a dose. Dose setting is thus deactivated in this context.

FIG. 2 shows injection device 30 after cocking and after cocking cap 56 has been unscrewed. The latter is unscrewed before an injection in order to prepare the device for an injection. In response to the action of a cocking spring 172 (FIG. 7), latching peg 64 moves slightly in the proximal direction and comes to rest against the proximal edge of longitudinal latch opening 38 (cf. FIG. 2). In this position - before an injection - a desired injection dose can be set by rotating setting knob 32.

To read off the dose, magnifier 42 has two individual magnifiers 70, 72. Because of the large number of dose settings that are possible for an injection - in the present case, for example, thirty different settings between "0" and "58" units - the scale is printed in two rows on circumferential surface 69 (FIGS. 9 and 11) of dose-setting knob 32. FIG. 2A shows a development 69' of said circumferential surface 69. The scale has a first row 71 with the numbers "0", "4", "8", etc. and a second row with the numbers "2", "6", "10", "14", etc. A stop 75 marks the zero position. Lens 70 shows a number from first row 71 in magnified fashion, and lens 72 shows a number from second row 73 in magnified fashion (cf. FIG. 2). This makes possible an unequivocal readout, i.e. in FIG. 2 the dose that is set is 16 units. (In the present example, the dose can always be displaced by two units, i.e. can be set from "0", "2", "4", etc. units to "58" units.)

In the position as shown in FIG. 2, triggering of injection device 30 is possible. This is done by pressing on clip 40 in the direction of a force vector 74 (FIG. 1). Latching peg 64 is thereby pressed radially inward by radially inwardly projecting protrusion 44. Cocking spring 172 (FIG. 7) then causes first an insertion of injection needle 76 (FIG. 4) and then an injection, through the inserted needle 76, of the injection dose that was set. This is described below with reference to FIGS. 24 and 25. This is therefore a device comprising a hidden needle 76, i.e. the latter is not visible to the patient, and the injection operation proceeds automatically after triggering.

Device 30 is thus cocked by screwing in cocking cap 56, and by unscrewing cocking cap 56 is brought into the position as shown in FIG. 2, in

which the desired dose can be set and then injected.

FIG. 3 shows injection device 30 in the position as shown in FIG. 1, the proximal region being depicted cut away. Cartridge 52, with fluid 53 contained in it, is visible. Cartridge 52 is located in a cartridge holder 80 that has at its proximal end a tapered neck 82 and is equipped there with an external thread 84. Cartridge 52 projects with its neck 86 into this neck 82. It is equipped at its proximal end with a rubber membrane 88 that is perforated, during use, by distal part 90 of needle 76. Needle 76, 90 is mounted on a usual needle holder 92 that is screwed, with its internal thread, onto external thread 84 of cartridge holder 80. In the cocked state it is protected by cocking cap 56 and is then not visible.

As FIG. 3 clearly shows, cocking cap 56 rests with a cylindrical segment 56A against needle holder 92, and biases the latter in the distal direction. Latching knob 64 thereby moves into its distal position in recess 38, as depicted in FIGS. 1 and 3, and setting knob 32 is deactivated as already described.

If the patient has forgotten to screw on a needle 76, needle holder 92 is absent and device 30 cannot be cocked, because cylindrical segment 56A of cocking cap 56 now projects into cavity 98 of cartridge holder 80, as shown in FIG. 16. Latching knob 64 is then in the position as shown in FIG. 17, which in FIG. 3 is labeled 64', i.e. in this state cocking and injection are not possible. This ensures that without needle 76, injection device 30 cannot be cocked.

FIG. 4 shows injection device 30 in the state after an injection. Needle 76 projects out of proximal barrel part 50. Cartridge holder 80 has an annular collar 100, and this rests against a damping ring 102 that is braced against an annular shoulder 104 on the inner side of proximal barrel part 50. This is the proximal end position of cartridge holder 80.

Located in cartridge 52, in the usual way, is a rubber piston 106, and during an injection (after the insertion of needle 76), the latter is displaced by a plunger 108 in the proximal direction in order to expel from cartridge 52 the quantity of fluid previously set with setting knob 32.

FIG. 5 depicts, in exploded and three-dimensional fashion, the various parts of the proximal segment of injection device 30. Provided in proximal barrel part 50 is internal thread 60 into which external thread 58 of cocking cap 56 can be screwed in order to cock the injection device. This is a coarse thread with a trapezoidal thread cross section.

Middle barrel part 48 has at its proximal end an external thread 109 that serves to connect with an internal thread 110 at the distal end of

proximal barrel part 50. Middle barrel part 48 also has, at its proximal end on the inner side, short axial splines 112 that provide longitudinal guidance for a longitudinal rib 111 (or multiple longitudinal ribs) on the outer side of cartridge holder 80. These longitudinal ribs 111 prevent cartridge holder 80 from rotating as long as injection device 30 is in its ready-to-operate state. This longitudinal guidance is deactivated during replacement of a cartridge 52, i.e. longitudinal ribs 111 then slide out of axial splines 112 (cf. FIGS. 26 through 32 below). The longitudinal guidance provided by parts 111, 112 prevents cartridge holder 80 from rotating relative to barrel part 50 while an injection needle 76 is being replaced, and thereby detaching from a front adapter part 116 (FIGS. 6 and 14).

Cartridge holder 80 has at its distal end an external thread 114 that serves to connect with an internal thread 115 (FIGS. 6 and 14) of front adapter part 116. External thread 114 has an interruption 118 which has a specific function in the context of cartridge replacement. This is described below.

Neck 82 of cartridge holder 80 is configured in the manner of a socket wrench, and for that purpose has a diagonally extending groove 120 that makes possible a rotation of adapter part 116 (cf. FIG. 6) when said neck 82 is inserted into adapter part 116, which is of correspondingly complementary configuration so that it can engage into groove 120 (cf. FIGS. 14 and 20). Parts 120 and 226 thus fit into one another like a key and lock.

Needle 76 and cartridge 52 are not depicted in FIG. 5 so as not to overload the depiction with too many details.

FIGS. 6 through 9 depict, in exploded and three-dimensional fashion, the remaining parts of injection device 30. The depiction is in some cases highly schematized in order to facilitate comprehension of the invention. FIG. 9 is depicted at an enlarged scale as compared to FIGS. 6 and 7, for better depiction of details.

In FIG. 6, front adapter part 116 with its internal thread 115 is followed by a rear adapter part 122 that, during assembly, is joined rotatably but axially nondisplaceably to the front (proximal) adapter part 116, a torque-dependent coupling (K7 in FIG. 18) being provided between parts 116 and 122.

Next comes a guide part 124 that provides axial guidance of plunger 108 (FIGS. 7 and 8) and that during assembly is joined nonrotatably but axially displaceably to rear adapter part 122. This is followed by a stop ring 126 whose function will be explained below and which is installed in an annular groove 262 of rear adapter part 122.

Distal barrel part 36 receives an internal tube 130 in the rotational

position depicted in FIG. 6, i.e. a longitudinal slot 136 of internal tube 130 aligns with latch cutout 38 of barrel part 36. Internal tube 130 forms, over a short portion of its longitudinal extension, the annular part 46 that is visible in FIG. 1 and has as rotation preventer a protrusion 133 that projects into a corresponding aperture 133' of barrel part 36. At its proximal end, internal tube 130 is equipped with an external thread 132 that serves to connect with an internal thread 139 (FIG. 5) at the distal end of middle barrel part 48. Internal tube 130 is equipped over a portion of its length with internal axial splines 134. Its axial longitudinal groove 136 provides longitudinal guidance for latching member 64 so that the latter cannot rotate in barrel 36. Internal tube 130 furthermore has, in the region of its distal end, two lateral latch cutouts 138, 140 for latching with corresponding barbs 142 on a molded part 144 (depicted in FIGS. 9 and 10) that carries, inter alia, clip 40.

FIG. 7 shows, on the right next to distal barrel part 36, front part 148 and rear part 150 of a so-called setting sleeve 151 that serves for dose setting, i.e. as a setting member. Upon assembly, parts 148 and 150 are immovably joined to one another by latching and then form setting sleeve 151. The latter is rotated during dose setting and thereby displaces plunger 108, which in the assembled state engages with its external thread 159 into internal thread 152 of part 148, in the proximal direction.

Part 148 guides, in an annular groove 153, a support part 155 which carries latching peg 64 and is pressed radially outward by a compression spring 157 (cf. FIG. 7).

FIG. 8 shows plunger 108 at enlarged scale. Its external thread 159 is a rectangular coarse thread. Plunger 108 has two longitudinal grooves 156, 158. In the assembled state, a protrusion 160 (FIG. 6) of guide part 124, serving as an engagement member, engages into longitudinal groove 156, thereby preventing any rotation of plunger 108 relative to the barrel of injection device 30 during dose setting and injection.

As depicted, a micro-tooth set 162 somewhat like that of a toothed rack is present in longitudinal groove 158. Tooth set 162 extends from proximal end 164 approximately as far as a stop 166 in groove 158, in this case over approximately two-thirds of the longitudinal extent of plunger 108. In the region of its distal end 168, plunger 108 is equipped with an annular groove 170 which serves as latching element and which has, during replacement of a cartridge 52, a function that will be explained in more detail below with reference to FIG. 29.

In FIG. 7, 172 designates the cocking spring which stores the energy for an injection and, in the assembled state, is braced at its proximal end 174 via a plain washer 176 against part 148, and biases the latter in the proximal direction.

With its distal end 178, spring 172 is braced against an annular

shoulder 180 of molded part 144 (FIG. 9). The latter is made of a flexible plastic and has a resilient latching element 182 comprising a latch protrusion 184 that, during dose setting, engages into splines 220 (FIG. 7) of part 148 and causes clicking sounds upon rotation of part 148. These sounds allow blind patients to set the desired dose by counting the clicks. In addition, after dose setting latch protrusion 184 immobilizes part 148 in its set position by engagement into splines 220, i.e. acts like a coupling (K3 in FIG. 18) that is disengaged in the course of an injection.

Magnifier 42 is shown only schematically in FIG. 9. It is introduced from below into a cutout 186 of molded part 144. This is symbolically indicated by a dot-dash line 188.

A return spring for setting knob 32 is labeled 190 in FIG. 9. It is a torsion spring. Its distal end 192 is nonrotatably joined to setting knob 32, and its proximal end 194 to molded part 144. After an injection, this spring 190 rotates setting knob 32 back into its zero position, in which a dose of "0" can be read off through magnifier 42.

Setting knob 32 has on its inner side splines 196 which interact with corresponding splines 198 of part 150 of setting sleeve 151. (FIG. 9 is drawn at a larger scale than FIG. 7.) An opening 199 (FIG. 11) at the distal end of setting knob 32 is closed off by a cover 200 (FIGS. 9 and 35).

FIG. 10 shows molded part 144 in longitudinal section. Its right-hand part 202 is located practically entirely in the interior of distal barrel part 36. The latter has a lateral aperture 204 (FIG. 7), and through this, clip 40 projects outward and prevents molded part 144 from rotating. Longitudinal ribs 203 provide low-friction lateral guidance for spring 172, which is depicted in FIG. 7.

FIG. 11 shows setting knob 32 in longitudinal section. Its internal splines 196 extend over approximately two-thirds of the total length of this part. The latter thus has, at the distal end, a short region 206 that has no splines, and has a longer proximal region 208 where splines also are not present. On its outer side, setting knob 32 has an annular ridge 210 for engagement into a corresponding annular groove 212 (FIG. 6) of distal barrel part 36. It is clipped into this annular groove 212 during assembly. It also has an annular space 211 which receives return spring 190 that is depicted in FIG. 9.

FIG. 12 shows part 150 of setting sleeve 151. The latter has at the proximal end two radially resilient hooks 212 (FIG. 7) for positive engagement into corresponding cutouts 214 of part 148 of the setting sleeve. This engagement is symbolized in FIG. 13 by a dot-dash line 216.

As is clearly evident from FIGS. 11 and 12, outer splines 198 of part 150 are configured for positive engagement into inner splines 196 of setting knob 32. When outer splines 198 are in engagement with inner splines 196, part 150 - and with it part 148 - can then be rotated by turning setting knob 32,

i.e. it is possible to set a dose.

When outer splines 198 are located in region 206, setting knob 32 then cannot transfer any torque to part 150. This is the free-wheeling neutral position of setting knob 32, which was explained in detail with reference to FIGS. 1 and 3.

When outer splines 198 are located in region 208, setting knob 32 also cannot transfer any torque to part 150. This is the position after an injection; in this position, setting knob 32 is turned back into its zero position by return spring 190 (FIG. 9) so that the next dose setting operation can begin again at the "0" position.

As FIG. 13 shows particularly clearly, part 148 has at its distal end external splines 220 that, when device 30 is in the cocked state, interact with latch protrusion 184 (FIG. 10) in order to generate clicking sounds during dose setting and to "immobilize" a dose once it has been set, i.e. to prevent inadvertent resetting of that dose.

Part 148 furthermore has external splines 222 at its proximal end. When the device is in the cocked state, these splines 222 are not in engagement with internal splines 134 of internal tube 130 (FIG. 6), so that parts 148 and 150, which together form setting sleeve 151, are freely rotatable so that the dose can be set. This state is depicted in enlarged fashion in FIG. 17 (coupling K4 open; alternatively, in FIG. 17 coupling K4 could also be closed in order to block any rotation of setting sleeve 151 by the patient).

During an injection, part 148 (together with part 150) is moved in the proximal direction, and its splines 222 thus come into engagement with internal splines 134 of internal tube 130 (indicated only schematically in FIG. 13). This situation is depicted, for example, in FIG. 24 (coupling K4 closed).

As soon as axial internal splines 134 engage into external splines 222, setting sleeve 151 is prevented from rotating relative to internal tube 130, i.e. the injection dose that has been set cannot change during the injection operation. The tooth count of splines 220 equals the tooth count of splines 222. In the present exemplary embodiment, this count is thirty-two teeth each to allow a total of thirty dose settings from 0 to 58 units (cf. FIG. 2A and FIG. 36). (Two teeth are not used for dose setting; cf. FIG. 36 and its accompanying explanations.)

FIG. 14 shows front adapter part 116 and rear adapter part 122 in

exploded fashion, at enlarged scale, and in a three-dimensional depiction. Front adapter part 116 has a cutout 224 with protrusions 226 which together serve to connect to diagonal groove 120 (already explained; FIG. 5) of cartridge holder 80 in order to make possible, by means of the (rotated) cartridge holder 80, a rotation of front adapter part 116. Such rotation can become necessary in unfavorable circumstances during cartridge replacement.

Front adapter part 116 furthermore has two axial plastic springs 228 which, as shown in FIG. 15, in the assembled state rest against cartridge 52 and apply to it a force in the proximal direction (cf. also FIG. 20).

Front adapter part 116 furthermore has a resilient tongue 230 which extends in the axial direction and on whose free end, on the radially inner side, is provided a latching member 232 (with a triangular cross section) that interacts with corresponding latch protrusions 234 of rear adapter part 122 and forms with them a slip coupling that becomes effective during cartridge replacement and prevents the patient, when screwing cartridge holder 80 onto front adapter part 116, from exerting too much torque on front adapter part 116 and thereby damaging it. Specifically, if too high a torque is exerted by the patient in the direction of arrow 236 (FIG. 14), latching member 232 then slips over latch protrusions 234 and front adapter part 116 rotates relative to rear adapter part 122, so that the injection device cannot be damaged.

During assembly, the two adapter parts 116, 122 are releasably latched to one another by the fact that an annular ridge 238 of front adapter part 116 is snapped into an annular groove 240 of rear adapter part 122, as shown by FIG. 15. Annular groove 240 is located on two axial protrusions 252, 254.

Front adapter part 116 also has a radially inwardly projecting resilient latching member 242 that serves to snap into cutout 118 (FIG. 5) of outer thread 114 provided on cartridge holder 80. After a cartridge replacement, latching member 242 snaps into this cutout 118. When an old cartridge 52 is to be removed, front adapter part 116 is first rotated along by the rotation of cartridge holder 80 in the direction of an arrow 237 (FIG. 14), since latching member 242 causes a torque to be transferred from cartridge holder 80 to adapter part 116. This rotational movement serves to reset plunger 108, as will be described below with reference to FIGS. 27 through 29. Only when plunger 108 has been completely reset, i.e. moved in the distal direction to a stop (K2 in FIG. 29), does latching member 242 snap out of cutout 118, and cartridge holder 80 is unscrewed from front adapter part 116 so that cartridge 52 can be exchanged. This ensures that during a cartridge replacement, plunger 108 is automatically moved in the distal direction to a stop (K2 in FIG. 29). Plunger 108 is then releasably latched in this position by a latching member 320 (cf. FIGS. 28 and 29).

As FIG. 14 shows, ratchet teeth 234 are located on a tubular segment 246 of rear adapter part 122. This segment 246 has on its proximal region a radially resilient segment 248 that is equipped on its radially inward side

with ratchet teeth 250. These serve to engage into micro-tooth set 162 depicted in FIG. 8, and ratchet teeth 250 are therefore configured in substantially complementary fashion to micro-tooth set 162 (cf. FIG. 15). They form a slip coupling with the latter, i.e. when a displacement force exceeding a defined magnitude occurs between ratchet teeth 250 and micro-tooth set 162, ratchet teeth 250 slip over the teeth of micro-tooth set 162. Such is the case in the final phase of an injection and upon replacement of a cartridge, since in that context plunger 108 must be reset into its distal end position (cf. FIGS. 27, 28, and 29).

Axial protrusions 252, 254 extend in the proximal direction, and their purposes include continuously maintaining a predefined clearance between front adapter part 116 and rear adapter part 122, and rotatably mounting front adapter part 116. The radially outer side of rear adapter part 122 is equipped with external splines 256 which are configured in complementary fashion to internal splines 134 of internal tube 130 and engage into them as long as adapter part 122 is located in internal tube 130.

As FIGS. 14 and 15 show, rear adapter 122 also has on its distal end a tubular extension 260 that is equipped in its distal end region with an annular groove 262 which receives stop ring 126 depicted in FIG. 6. As shown in FIG. 15, tubular extension 260 has an axially extending orifice 264 through which protrusion 160 (cf. FIG. 6) of guide part 124 projects into the one longitudinal groove 156 of plunger 108 and thereby joins the latter nonrotatably, but axially displaceably, to guide part 124.

As shown in FIG. 6, guide part 124 has two axial protrusions 266, 268 which lie diametrically opposite one another and project in the proximal direction. Because of annular ridge 238 (FIG. 14) on front adapter part 116, the inside diameter of protrusions 266, 268 increases in their proximal region 266', 268'. Protrusions 266, 268 are axially guided by two guide openings 272, 270, approximately complementary to them, of rear adapter part 122, i.e. between adapter part 122 and guide part 124 a relative rotational movement is not possible, but an axial displacement is. The latter is limited in the one direction by stop ring 126 (cf. FIG. 15) and in the other direction by contact of axial protrusions 266, 268 against front adapter part 116 (cf. FIG. 25) or by contact of guide part 124 against rear adapter part 122. Guide part 124 is equipped on its periphery with external splines 274 which, during an injection, are guided in internal splines 134 of internal tube 130. Since guide part 124 is joined nonrotatably to adapter part 122 and to plunger 108, the rotational position of these parts is determined by the rotational position of guide part 124.

When injections take place, guide part 124 is always joined nonrotatably, but axially displaceably, to internal tube 130. Upon replacement of a cartridge this nonrotatable connection is disengaged (cf. FIGS. 26-32), and guide part 124, as well as parts 108 and 122 nonrotatably joined to it, can then rotate relative to barrel 36, while setting sleeve 151 is in engagement by way of its external splines 222 with internal tube 130 and therefore cannot be rotated. Simple resetting of plunger 108 is thereby possible, as will be described below.

On its distal side, guide part 124 has a tubular extension 276 on whose outer side (as shown in FIG. 15) an annular groove 278 is provided.

As shown in FIG. 7, proximal part 148 of setting sleeve 151 is equipped on its proximal side with a cutout 280 on which four radially inwardly projecting latching segments 282 are provided; upon assembly, these are clipped into annular groove 278 of guide part 124 and thereby join setting sleeve 151 rotatably, but axially nondisplaceably, to guide part 124.

Since part 148 of setting sleeve 151 is in engagement by way of its internal thread 152 with external thread 159 of plunger 108, and since the latter is prevented from rotating by protrusion 160 of guide part 124, a rotation of parts 150, 148 causes an axial displacement of plunger 108, of the two adapter parts 116, 122 joined to it via teeth 250 (FIG. 14), and thus also of cartridge holder 80; in other words, as a dose is set, all these parts are displaced together over a distance that corresponds to the desired dose setting. This will be explained in more detail below with reference to FIG. 23.

FIGS. 16 and 17 show what happens when the patient attempts to cock injection device 30 in the absence of a needle. In this situation, proximal opening 98 of cartridge holder 80 is not covered by needle holder 92 (FIG. 3), and part 56A of cocking knob 56 projects through said opening 98 and rests against the proximal end of cartridge 52. As FIG. 17 shows, in this case latching peg 64 is not moved far enough in the distal direction that it can snap into latch opening 38, i.e. it is not possible to cock the device.

In this situation, in the position as shown in FIG. 16 it is theoretically possible to set a dose, since setting knob 32 is in engagement with dose-setting sleeve 151; but because no needle is present, fluid 58 in cartridge 52 acts like a rigid body which presents to any displacement of plunger 108 a resistance that cannot be overcome, thus preventing any such displacement. Dose setting in this position is therefore prevented, and after cocking cap 56 is unscrewed, device 30 returns to its uncocked position as shown in FIG. 4, so that the patient is forced to screw on a needle 76 so that he or she can cock device 30, then set a dose, and then inject.

The present invention makes use of the interaction of various coupling elements, partly in the form of position-dependent couplings and partly in the form of force-dependent couplings, and of a coupling that couples two elements nonrotatably to one another but allows an axial displacement between them. FIG. 18 shows these couplings in a schematic overview.

Between external splines 198 (FIG. 12) of setting sleeve 151 and internal splines 196 (FIG. 11) of setting knob 32, there exists a position-dependent coupling K1 whose mode of operation has already been described. It makes possible automatic resetting of setting knob 72 to "0" during an injection, and it deactivates setting knob 32 when the device is in its cocked position of FIG. 3.

A force- and position-dependent latching coupling K2 is provided between the distal end of plunger 108 and the distal end of setting sleeve 151. This coupling K2 is described in more detail below with reference to FIGS. 28 and 29. It has a function in the context of replacement of cartridge 52.

A force- and position-dependent latching coupling K3 is provided between barrel-mounted latching member 184 and external splines 220 of setting sleeve 151. This coupling K3 is engaged when the device is in its cocked position, and serves to store the desired dose setting. K3 is opened during an injection, but the stored information cannot be lost because the function of coupling K3 is seamlessly taken over by a coupling K4. (In order to facilitate comprehension, in FIG. 18 latching member 184 is merely indicated with dot-dash lines.)

Coupling K4 is a position-dependent coupling, and is provided between external splines 222 at the proximal end of setting sleeve 151 and internal splines 134 of internal tube 130. Coupling K4 is open as long as injection device 30 is in its cocked position, so that setting sleeve 151 can be rotated there in order to set a dose.

Directly after the beginning of an injection and during the entire course of an injection, coupling K4 is closed (cf. FIG. 15), i.e. setting sleeve 151 is then guided nonrotatably but axially displaceably in internal tube 30. Coupling K4 is also closed when a cartridge 52 is being replaced.

A position-dependent coupling K5 is provided between external splines 274 of guide part 124 and internal splines 134 of internal tube 130, and also between external splines 256 of rear adapter part 122 and internal splines 134. This coupling K5 is always closed as long as the device is ready for injection. It is opened when a new cartridge 52 is introduced into the device,

since, in this context, parts 116, 122, and 124 must be rotated relative to setting sleeve 151 so that plunger 108 can be brought into the correct position.

An axially displaceable coupling K6 is provided between protrusions 266, 268 of guide part 124 and rear adapter part 122. This coupling makes dose setting possible, as will be described below with reference to FIG. 23.

A slip coupling K7 is provided between front adapter part 116 and rear adapter part 122. It is described in more detail with reference to FIG. 14, and is formed by resilient catch 232 of front adapter part 116 and ratchet teeth 234 of rear adapter part 122. This slip coupling K7 becomes functional, if applicable, during cartridge replacement.

A force-dependent slip coupling K8 is provided between rear adapter part 122 and plunger 108. It is formed by micro-tooth set 162 (FIG. 8) of plunger 108 and the corresponding tooth set 250 (FIG. 14) on rear adapter part 122. It becomes functional in the course of an injection in order to make possible the expulsion of injection fluid 53 from cartridge 52, and also during replacement of a cartridge 52.

A torque-dependent coupling K9 is provided between cartridge holder 80 and front adapter part 116. It is formed by cutout 118 (FIG. 5) of external thread 114 and the radially inwardly projecting part 242 (FIG. 14) of front adapter part 116. This coupling K9 becomes functional when a cartridge 52 is replaced, and ensures that plunger 108 is brought into the correct position during cartridge replacement.

A position-dependent coupling K10 is provided between longitudinal ribs 111 of cartridge holder 80 and internal splines 112 of middle barrel part 48. Coupling K10 is engaged as long as injections are taking place, and prevents cartridge holder 80 from rotating relative to front adapter part 116 while injection needle 76 is being replaced. Coupling K10 is automatically opened during cartridge replacement, since cartridge holder 80 then needs to be unscrewed from front adapter part 116.

The interaction of couplings K1 through K10 is evident from the description of the Figures below. For example, in FIG. 15 couplings K4 and K5 are closed and coupling K3 is open.

FIG. 19 once again shows injection device 30 in its position as shown in FIG. 3, but in a continuous longitudinal section. The labeling of the parts is the same as in the previous Figures, so that reference can be made thereto. It is evident that during cocking, protrusions 266, 268 make contact against

front adapter part 116, i.e. parts 124, 122, 116 are (after an injection) completely pushed together in telescoping fashion, just as in FIGS. 16 and 17. They can therefore transfer the cocking force of cocking cap 56 directly to spring 172 and compress the latter until latching element 64 snaps into latch cutout 38.

Coupling K1 is open, i.e. dose setting is not possible.

Coupling K2 is open, i.e. plunger 108 is not releasably latched to part 150.

Coupling K3 is activated, i.e. latching element 184 is engaged into splines 220.

Coupling K4 is open, i.e. setting sleeve 151 is free to rotate.

Coupling K5 is closed, i.e. guide part 124 and rear adapter part 122 are not rotatable relative to barrel 36.

Coupling K8 is engaged, i.e. the two adapter parts 116, 122 must follow the axial movements of plunger 108.

Coupling K10 is engaged, i.e. longitudinal ribs 111 of cartridge holder 80 are guided by internal splines 112 of middle barrel part 48, and cartridge holder 80 is thereby prevented from rotating.

FIG. 20 shows substantially a plan view of the inner side of front adapter part 116 in its assembled state. For the sake of brevity, the reader is referred to the explanations of FIG. 14. Particularly evident is cutout 224, which is configured for engagement with the socket wrench-like end 120 (FIG. 5) of cartridge holder 80. Cutout 98 of cartridge holder 80 has a diameter which allows plunger 108 to slide through it.

FIG. 21 shows the manner in which parts 252, 254, and 268 engage interdigitally into one another. As already described, parts 266, 268 serve to join parts 122, 124 nonrotatably to one another but make them axially displaceable relative to one another, as is particularly clearly apparent from FIG. 6.

FIG. 22 shows the injection device in the position as shown in FIG. 2 and in longitudinal section. To prepare an injection, the patient has unscrewed cocking cap 56 (FIG. 2) from thread 60, and the cocked spring 172 has displaced the internal parts of the device approximately 2 mm in the proximal direction so that latching knob 64 is in contact against the proximal end of cutout 38.

As a result, coupling K1 is now engaged, i.e. setting sleeve 151 can be rotated, by turning setting knob 32, in order to set the desired injection dose.

Coupling K3 is still in engagement, i.e. latching catch 184 is engaged into splines 220.

Coupling K4 is not engaged, i.e. the setting sleeve is rotatable relative to the barrel for dose setting.

Coupling K5 is engaged, i.e. guide part 124, rear adapter part 122, and plunger 108 cannot rotate relative to barrel 36.

Coupling K8 is engaged, i.e. rear adapter part 122 is coupled to plunger 108 and cartridge holder 80 in the axial direction as well, so that in the axial direction, these parts can move only together.

Coupling K10 is also engaged.

In this situation the proximal tip of injection needle 76 is at a spacing Z from the proximal end of barrel part 50. This is the maximum spacing, and setting a dose causes it to become smaller, as will be described below with reference to FIG. 23.

In FIG. 23, setting knob 32 is rotated clockwise (arrow 300 in FIG. 23) when viewed in the direction of an arrow 302, i.e. when viewed in the proximal direction.

Since coupling K1 is engaged, setting sleeve 151 - which is immobilized in its axial position by latching member 64 - is thereby rotated. With its internal thread 152, setting sleeve 151 screws plunger 108 in the proximal direction, since the latter is prevented from rotating by the engagement of part 160 of guide member 124.

Coupling K4 is open, i.e. setting sleeve 151 can rotate freely.

Coupling K5 is closed, i.e. guide member 124 and rear adapter part 122 are prevented from rotating relative to barrel part 36.

Upon displacement in the proximal direction, plunger 108 carries rear adapter part 124 along by way of coupling K8 (cf. description of FIG. 18). Said part 124 displaces front adapter part 116 that is joined to it, and with the latter cartridge holder 80, in the proximal direction over a distance Y that corresponds to the dose to be injected. The spacing between the proximal end of needle 76 and the proximal end of barrel part 50 is thereby decreased in FIG. 23 from Z (FIG. 22) to (Z - Y). Needle 76 is still not visible to the patient.

After the dose to be injected has been set, injection device 30 is then ready for an injection. The dose Y that was set remains stored, since coupling K3 prevents any rotation of setting sleeve 151.

For an injection, the patient places the device on the part of the body where an injection is to be performed, for example on the buttocks, and then, as shown in FIG. 24, presses with a symbolically indicated force F on clip 40 so that the latter is deflected inward and, with its protrusion 44, presses latching knob 64 inward so that the cocked injection spring 172 displaces setting sleeve 151 in the proximal direction. In this context, latching knob 64 slides in axial longitudinal groove 136 (FIG. 6) of internal tube 130.

In this process, coupling K1 initially remains closed. Coupling K3 opens, since splines 220 slide out of latching element 184. During this sliding-out process, setting sleeve 151 slides with its external splines 222 (FIG. 13) into internal splines 134 (FIG. 6) of internal tube 130, and is thereby uninterruptedly prevented from rotating, so that the dose set by the patient remains stored without change. Setting sleeve 151 brings about, by way of its internal thread 152, an axial displacement of plunger 108 in the proximal direction. Since the latter is joined via coupling K8 to rear adapter part 122, the latter, and with it front adapter part 116 and cartridge holder 80, is also moved in the axial direction so that (as shown in FIG. 24) needle 76 is inserted into the patient. This is therefore the operation by which needle 76 is inserted.

Coupling K5 remains closed in this context, i.e. guide member 124 cannot rotate relative to barrel part 36. Guide part 124 is in direct drive connection with setting sleeve 151, so that guide member 124 is also displaced in the proximal direction, but cannot rotate and also (by way of its engagement member 160) prevents any rotation of plunger 108.

During the needle insertion operation, cartridge holder 80 is moved in the proximal direction until its annular collar 100 strikes against damping ring 102, which is braced against annular shoulder 104. This terminates the movement of cartridge holder 80 in the proximal direction. Coupling K10 remains continuously engaged; in FIG. 24, internal splines 112 of middle barrel part 48 are in engagement only with the distal end region of longitudinal ribs 111, as depicted in FIG. 24.

FIG. 25 shows the further progress of an injection. Since annular collar 100 has come to a stop against damping ring 102, cartridge holder 80 can move no farther in the proximal direction, and coupling K8 is thereby disengaged, i.e. teeth 250 of part 248 (FIG. 14) now slide over micro-tooth set 162 (FIG. 8) of plunger 108 so that the latter is moved, independently of cartridge holder 80, farther in the proximal direction, thereby displacing piston 106 in cartridge 52 over the distance Y that was set, and thus expelling from needle 76 the dose of medication 53 set by the patient, as indicated symbolically in FIG. 25 at 304.

During this movement, front adapter part 116 and rear adapter part 122

no longer change their axial position in barrel part 48, i.e. they remain stationary, while setting sleeve 151, and guide part 124 joined to it, continue to move over distance Y that was set. Since plunger 108 is axially joined to setting sleeve 151 by the latter's thread 152, plunger 108 also moves over distance Y in the proximal direction and displaces piston 106, since cartridge 52 cannot move any farther in the proximal direction.

During its axial movement, setting sleeve 151 slides with its external splines 198 out of internal splines 196 of setting knob 32, i.e. coupling K1 is opened. Torsion spring 190 can therefore turn setting knob 32 back into its zero position, as symbolized in FIG. 25 by rotation arrow 310.

During the final phase of an injection, the inner parts of injection device 30 are thus pushed together, in telescoping fashion, a specific distance Y over which they had previously been moved apart from one another when the dose was set (FIG. 23).

Couplings K4 and K5 are, in this context, engaged. Coupling K8 is open during the final phase of an injection, but comes back into engagement immediately thereafter. Coupling K10 remains continuously engaged.

Coupling K5 is formed here by the fact that the distal end of external splines 274 (FIG. 6) of guide part 124 is in engagement with the proximal end region of internal splines 134. Plunger 108 is prevented from rotating by guide part 124 (part 160 of guide part 124).

After the injection, the patient pulls needle 76 out of the tissue, replaces it with a new needle if applicable, and then screws on cocking cap 56, so that device 30 once again assumes the state shown in FIGS. 3 and 19. In this state the device can be transported, for example in a case or purse. If insulin is to be injected with the device, refrigerated storage (in a refrigerator) is desirable.

When the contents 53 of a cartridge 52 are exhausted, the patient sees this through viewing window 54 (FIG. 5) or 54A (FIG. 34). As shown in FIG. 15, plunger 108 has stops 166, one of which (in this case) strikes against guide member 160 of guide part 124, thus preventing dose setting and indicating to the patient that he or she must now replace cartridge 52. In this situation the patient can administer only the remaining quantity of ingredient that is present in cartridge 52.

In the context of a cartridge replacement, FIG. 26 shows that proximal barrel part 50 is unscrewed from the uncocked injection device 30. This is symbolized in FIG. 26 by a rotation arrow 312.

Since stop 102, 104 now does not exist, front adapter part 116 is displaced, in response to the action of spring 172, until it comes to a stop against the distal-side inner rim 314 (FIG. 5) of internal splines 112 of

middle barrel part 48. Coupling K5 thus opens, while coupling K4 remains engaged. Coupling K10 also opens, i.e. cartridge holder 80 can now be rotated relative to middle barrel part 48. Coupling K1 also remains open, i.e. it is not possible to set a dose.

FIG. 27 shows the injection device after proximal barrel part 50 has been unscrewed. As already explained, cartridge holder 80 can now be rotated in the direction of a rotation arrow 317, i.e. counterclockwise when viewed in the direction of an arrow 315.

Coupling K9 (FIG. 18) initially remains closed, i.e. resilient tongue 242 (FIG. 14) projects into cutout 118 (FIG. 5) of external thread 114. The rotational movement in the direction of arrow 317 is therefore transferred to front adapter part 116 and from it to rear adapter part 122 and guide part 124. The latter, by way of its engagement member 160, rotates plunger 108, since coupling K5 is open. Since coupling K4 is engaged, plunger 108 is screwed in the distal direction in the direction of arrow 316. Teeth 250 of rear adapter part 122 thus slide (FIG. 14) over micro-tooth set 162 (FIG. 8) of plunger 108. The latter is screwed in the distal direction until its stop 318 strikes against engagement member 160 of guide part 124. This state is depicted in FIG. 28.

Plunger 108 now can move no farther in the distal direction and parts 116, 122, and 124 consequently can no longer rotate, so that coupling K9 is now disengaged and cartridge holder 80 is unscrewed from front adapter part 116.

This state is shown in FIGS. 28 and 29. Plunger 108 is parked in the interior of barrel 36, 48, and its distal end 168 is in latching engagement, by way of annular groove 170 thereon, with a radially inwardly projecting collar 322 of part 150. In this state latching coupling K2 is thus engaged, and immobilizes plunger 108.

As shown in FIG. 30, empty cartridge 52 is now removed from the unscrewed cartridge holder 80; and as shown in FIG. 31, a full cartridge 52 is inserted into cartridge holder 80.

As shown in FIG. 32, cartridge holder 80 with the new cartridge 52 is screwed back onto front adapter part 116. Viewed in the distal direction 315, cartridge holder 80 is rotated clockwise for this purpose. Since latching coupling K2 as shown in FIG. 29 is closed, plunger 108 initially cannot move in the proximal direction; as a result, any rotational movement of guide part 124, rear adapter part 122, and front adapter part 116 is also blocked, so that cartridge holder 80 is screwed completely into front adapter part 116 until latching coupling K9 comes into engagement there. Only then is latching coupling K2 disengaged by the torque exerted by the user, and plunger 108 is displaced in the proximal direction until it comes to rest gently against piston 106.

Since cartridge 52 is sealed in fluid-tight fashion, piston 106 cannot be displaced in it. If the user tries to use force to keep turning cartridge holder 80 in the direction of rotation arrow 321 (FIG. 32), coupling K7 takes effect, i.e. latching catch 232 (FIG. 14) slides over ratchet teeth 234. In this situation the user therefore cannot damage injection device 30 even by using force, since if a predefined torque in this rotation direction is exceeded, the effect of coupling K7 is to allow front adapter part 116 to rotate freely relative to rear adapter part 122. Coupling K7 therefore acts, in the direction just described, as a slip coupling. This is not necessary in the opposite direction, since in this direction cartridge holder 80 is unscrewed from front adapter part 116.

Slip coupling K7 prevents the patient from elastically compressing rubber piston 106 by exerting too much torque. The consequence of this would be that in FIG. 33, after needle 76 (FIG. 3) is screwed on, injection fluid 53 would spray out of said needle, which is undesirable. Coupling K7 prevents this.

As shown in FIG. 33, proximal barrel part 50 is now also screwed on (rotation arrow 324); coupling K10 is thereby closed, and injection device 30 is then in a position analogous to FIG. 25 and is once again completely ready to use, i.e. no further adjustment or testing operations are necessary. If air bubbles should be present in cartridge 52, these can be removed by spraying a small injection dose upward into the air. This is demonstrated to the patient during instruction at the hospital.

Screwing on barrel part 50 causes cartridge holder 80 to be displaced in the distal direction, because annular collar 104 of barrel part 50 displaces annular ridge 100 of cartridge holder 80 in the distal direction. Coupling K10 comes into engagement, and cartridge holder 80 is once again guided, with its longitudinal ribs 11, nonrotatably in splines 112 (FIG. 5). Coupling K5 also comes back into engagement, and coupling K4 remains engaged, blocking any displacement of plunger 108. Coupling K1 remains disengaged, so that dose setting is deactivated. In this position, the patient therefore cannot influence the position of plunger 108 if he or she plays around with the device. Coupling K3 is not engaged in this position. Parts 124, 122, 116 are still pushed together in telescoping fashion.

After an injection needle 76 is put in place, the device can be cocked by screwing in cocking cap 56 and is then in a transportable state.

FIG. 34 shows a variant in which a plurality of small holes 54A are used as the viewing window. This is the preferred approach in the context of the invention, since the patient cannot reach through said holes 54A and therefore cannot slow down an injection procedure with his or her fingers.

FIG. 35 shows the injection device of FIG. 34 from above, but at a larger scale than FIG. 34.

FIG. 36 schematically depicts splines 220 of setting sleeve 151 (FIG. 7) and latching member 184 (FIG. 8) which engages resiliently, during dose setting, into said splines 220. The dose settings from zero to "58" are indicated by way of example.

Splines 220 have a total of thirty-two teeth 221, so that the angle (mu) between two adjacent teeth is 360°/32 = 11.5°. Because of stop 75 (FIG. 9), two teeth are not used for dose setting.

This number of thirty-two teeth is used in the same fashion in spline sets 112, 134, 196, 198, 220, 222, 256, and 274, so that the parts of injection device 30 can easily slide into and out of one another. For this reason, these spline sets therefore also have the same angular position relative to one another, i.e. no "phase shift."

Note also the following with regard to operation: the distance L (FIGS. 25 and 39) that latching member 64 travels after it is triggered during an injection is always the same.

Insertion depth U (FIG. 25) of needle 76 also remains unchanged in normal circumstances. (An insertion depth adjustment can, of course, be used in order to adapt the insertion depth to the patient.)

What is different in the context of distance L is the portion Y that is used for the displacement of piston 106. This portion Y is defined before the injection, by the fact that parts 124 and 122 are moved that distance Y apart during dose setting (cf. FIG. 23), thus causing needle 76, even before the injection, to be displaced that distance Y in the proximal direction. The distance traveled by needle 76 during an injection is therefore shorter than L by an amount equivalent to distance Y, as explained with reference to FIGS. 22 and 23.

As will be explained below with reference to FIGS. 39 and 40, internal splines 134 (FIG. 6) have a length of approximately L, since they must prevent guide part 124 from rotating during the entire travel length L. At the end of an injection, guide part 124 is still, with the distal end of its splines 274, just in engagement with internal splines 134, as FIGS. 25 and 39 show; and before an injection begins, the situation (as shown in FIGS. 22 and 28) is that splines 222 of setting sleeve 151 are just about to engage with internal splines 134, for which reason splines 274 of the immediately adjacent guide part 124 are fully engaged with internal splines 134 (cf. FIGS. 22 and 38).

The result is to yield an injection device that is physically short and functions very reliably, and to simplify replacement of a cartridge 52.

FIG. 37 once again illustrates the couplings that become active during cartridge replacement.

Located between container 80 and front adapter part 116 is a disengageable connection (external thread 114, internal thread 115) that could, if applicable, also be configured as a bayonet closure or the like.

Coupling K9 (parts 118, 242) is located in this disengageable connection. When container 80 is opened, K9 causes plunger 108 to be displaced into the latched position as shown in FIG. 29.

Coupling K7 (latching member 232 - visible in FIG. 14 - and ratchet teeth 234) is located between front adapter part 116 and rear adapter part 122. When container 80 is closed, coupling K7 ensures that plunger 108 is brought only gently into contact against piston 106, and does not elastically deform it.

Coupling K6 (protrusions 266, 268 and cutouts 270, 272) is located between rear adapter part 122 and guide part 124. It allows adjustment of the axial spacing between parts 122, 124, and transfer of a torque between them.

Couplings K7 and K9 can optionally be combined, for example if a bayonet closure is used (instead of threads 114, 115) for container 80.

If coupling K9 is defective, the user can use proximal end 120 of container 80 as a socket wrench to turn front adapter part 116 by engaging into its part 226.

FIGS. 38 through 40 synoptically show various possible positions of couplings K4 and K5.

In FIG. 38, the device is cocked and - at a dose setting of zero - ready to be triggered. Coupling K4 is not engaged. Coupling K5 is engaged. The boundary between setting sleeve 151 and guide part 124 is located at point A, namely at the distal end of internal splines 134.

In FIG. 39, the injection is complete. Latching member 64 has traveled distance L. The boundary between parts 151 and 124 has moved to point B, which is at a spacing L from point A. Point B is located above the lower end of splines 134, i.e. the latter are longer than L so that in FIG. 39, coupling K5 can remain closed, i.e. the distal part of splines 274 remains in engagement with internal splines 134. Coupling K4 is engaged during the injection.

FIG. 40 shows the situation during cartridge replacement. The aforesaid boundary between parts 151 and 124 has shifted to point C. Coupling K4 is still closed, i.e. part 151 cannot rotate, and coupling K5 is open so that guide part 124 can be rotated during cartridge replacement, as already described in detail. The spacing between A and C corresponds approximately to the axial length of internal splines 134, and is greater than L.

Instead of the couplings depicted, other types of coupling can also be used, for example couplings that utilize magnets. If the device is, for example, controlled by a microprocessor or microcontroller, couplings can be actuated by electrical energy.

Many other variations and modifications are, of course, possible within the context of the present invention.

CLAIMS

1. An injection device comprising a container (80) for reception of a cartridge (52) which contains an injection fluid (53) and on whose proximal end an injection needle (76) can be mounted,

comprising a barrel (50, 48, 46, 36) in which said container (80) is displaceable between a proximal end position and a distal end position,

comprising a plunger (108), arranged in the barrel and serving to expel injection fluid (53) out of the cartridge (52), which plunger during an injection is guided in a guide member (124) axially displaceably but nonrotatably relative to the barrel, and which has an external thread (159) that is guided in an internal thread (152) of a setting member (151) serving to set the injection dose,

and comprising a frictionally engaging coupling (162, 250) - in the manner of a slip coupling - between the container (80) and the plunger (108), for transferring at least a portion of an axial movement of the plunger (108) to the container (80).

2. The injection device according to claim 1, in which the setting member (151) has associated with it a spring (172) for biasing the setting member (151) in the proximal direction,

and the setting member (151) can be displaced against the force of said spring (172) into a distal position (FIG. 3) and releasably latched there.

3. The injection device according to claim 2, wherein the setting member (151) can be displaced from the proximal end of the barrel into a distal position (FIG. 3) and releasably latched there.

4. The injection device according to claim 3, wherein for cocking the spring (172), a cocking member (56) is provided which can be joined, from the proximal end of the injection device (30), to a thread (60) of the injection device, in order to displace the container (80), using a distal end region of the cocking member (56), in the proximal direction.

5. The injection device according to one or more of the foregoing claims, wherein the setting member (151) is, in at least one distal position (FIG. 2), rotatable relative to the barrel of the injection device in order to make possible an axial displacement of the plunger (108) relative to the barrel for the purpose of setting an injection dose (Y).

6. An injection device comprising a container (80) for reception of a cartridge (52) which contains an injection fluid (53) and on whose proximal end an injection needle (76) can be mounted,

comprising a barrel (50, 48, 46, 36) in which said container (80) is displaceable between a proximal end position and a distal end position,

comprising a plunger (108), arranged in the barrel and serving to expel injection fluid out of the cartridge (52), which is guided in a guide member (124) axially displaceably but nonrotatably relative to the guide member,

and which has an external thread (159) that is guided in an internal thread (152) of a setting member (151),

comprising a cocking spring (172) biasing the setting member (151) in the proximal direction and, during an injection operation, causes displacement thereof into a proximal end position,

and against the force of which the setting member (151) can be displaced into a distal end position and releasably latched there,

comprising a first coupling arrangement (K4), for nonrotatable but axially displaceable coupling of the setting member (151) to the barrel, which is deactivated in the distal end position of the setting member (151),

and comprising a second coupling arrangement (K5), for nonrotatable but axially displaceable coupling of the guide member (124) to the barrel, which is activated in the entire region between the distal and proximal end positions of the guide member (124).

7. The injection device according to claim 6, comprising a connection (282), provided between guide member (124) and setting member (151), that joins said parts to one another rotatably but substantially axially nondisplaceably.

8. The injection device according to claim 6 or 7, wherein both the guide member (124) and the setting member (151) have external splines (274 and 222, respectively),

and said external spline sets have associated therewith internal splines (134) in the barrel (36), into which said external spline sets (222, 274) can engage, individually or together, by means of a longitudinal displacement of guide member (124) and setting member (151) occurring relative to the barrel (36).

9. The injection device according to claim 8, wherein the setting member (151) is equipped with a latching member (64), by means of which the setting member (151) can be releasably latched in a predefined axial position relative to the barrel (36) in which its external splines (222) are not in engagement with the internal splines (134) in the barrel (36).

10. The injection device according to claim 8 or 9, wherein the setting member is equipped with a latching member (64), by means of which the guide member (124) can be releasably latched in a predefined axial position relative to the barrel (36) in which its external splines (274) are in engagement with the internal splines (134) in the barrel (36).

11. The injection device according to claim 9 or 10, wherein the setting member (151) is rotatable relative to the latching member (64) provided on it.

12. The injection device according to one or more of claims 6 through 11, wherein the setting member (151) is biased by the cocking spring (172) in the proximal direction with interposition of an annular part (176).

13. The injection device according to one or more of the foregoing claims, wherein there is provided, between the container (80) for the cartridge (52) and the guide member (124), a drive connection which makes possible the transfer of a torque from said container (80) to the guide member (124).

14. The injection device according to claim 13, wherein the drive connection comprises at least one apparatus (118, 242; 232, 234) that limits, in at least one rotation direction, the torque transferable from the container (80) to the guide member (124).

15. The injection device according to claim 14, wherein the apparatus for limiting the torque is configured as a slip coupling (232, 234).

16. The injection device according to claim 15, wherein the slip coupling (232, 234) is effective for the rotation direction (FIG. 32: 321) in which a disengageable connection (115, 118) closing the container (80) is closed.

17. The injection device according to one or more of the foregoing claims, wherein a lock (111, 112) for locking rotation of the container (80), which is disengaged upon replacement of a cartridge (52), is provided.

18. The injection device according to claim 17, wherein the outer side of the container (80) is axially guided (FIG. 5: 112) in the inner side of a barrel part (48), and this axial guidance (111, 112) is deactivated when the barrel is opened in order to replace a cartridge (52).

19. The injection device according to one or more of the foregoing claims, wherein the container (80) can be closed and opened by means of a disengageable connection (115, 118), in particular a threaded or bayonet connection, so that a cartridge (52) can be introduced or removed.

20. The injection device according to claim 19, wherein the disengageable connection (115, 118) comprises a device (118, 242) for generating an elevated breakaway torque in order temporarily to necessitate an elevated torque upon its disengagement.

21. The injection device according to claim 19 or 20, wherein the disengageable connection (115, 118) comprises an element (116) that is connected via a drive connection (266, 268, 270, 272) to the guide member (124).

22. The injection device according to claim 21, wherein the drive connection (266, 268, 270, 272) enables an axial relative movement between said element and the guide member (124).

23. The injection device according to one or more of the foregoing claims, wherein the plunger (108) has associated with it a latch (FIG. 29: K2), dependent on the position of the plunger (108), which releasably latches the latter in a predefined position relative to the setting member (151).

24. The injection device according to claim 23, wherein upon replacement of a cartridge (52), latching is accomplished by means of the position-dependent latch (FIG. 29: K2) in order to immobilize the plunger (108) in a predefined position after opening and before closing of the container (80).

25. The injection device according to one or more of the foregoing claims, wherein at least one working action necessary for replacement of a cartridge (52) is used to influence the position of the plunger (108) relative to the setting member (151).

26. The injection device according to one or more of the foregoing claims, comprising a cocking spring (172) which is cocked before an injection and which, after an injection is triggered, causes an insertion of the injection needle (76) and an expulsion of fluid (53) from the cartridge (52) through the injection needle (76).

27. The injection device according to claim 26, wherein the spring (172) is cocked from the proximal end of the injection device (30).

28. The injection device according to claim 27, wherein the barrel (50) comprises a thread (60) in its proximal region; and a cocking member (56) is provided which is equipped with a thread (58) complementary to said thread (60) and is configured to displace the container (80), configured for reception of a cartridge (52), in the barrel in the distal direction (315).

29. The injection device according to claim 28, wherein a latching member (64) is provided which, after a defined displacement in the distal direction (315), snaps into a latch opening (38),

and said defined displacement travel can be achieved only if an injection needle (76) is installed.

30. The injection device according to one or more of the foregoing claims, wherein the setting member (151) can be coupled via a travel-dependent coupling (K1) to a setting element (32) for manual setting of the injection dose.

31. The injection device according to claim 30, wherein the travel-dependent coupling (K1) is out of engagement during cartridge replacement (FIGS. 26 through 32).

32. The injection device according to one or more of the foregoing claims, wherein upon dose setting, an axial spacing (Y) in the region between the setting member (151) and the container (80) is increased.

33. The injection device according to claim 32, wherein during an injection, the axial spacing (Y) that was increased upon dose setting is decreased, in particular to zero.

34. The injection device according to claim 33, wherein upon the decrease in the axial spacing (Y), a frictionally engaging coupling (162, 250) provided between the container (80) and the plunger (108) is disengaged in order to make possible a relative movement between container (80) and plunger (108).

35. The injection device according to one or more of the foregoing claims, wherein the plunger (108) is equipped with a micro-tooth set (FIG. 8: 162),

and in order to create a frictionally engaging coupling, a part (122) arranged displaceably relative to the plunger (108) comprises an engagement member (FIG. 14: 250) for disengageable engagement into said micro-tooth set (162).

36. An injection device comprising a barrel (50, 48, 46, 36),

comprising a plunger (108), arranged in said barrel and serving to expel injection fluid out of a container (52) containing an injection fluid,

which plunger is guided in a guide member (124) axially displaceably but nonrotatably relative to the guide member,

and which has an external thread (159) that is guided in an internal thread (152) of a setting member (151),

comprising a cocking spring (172) which biases the setting member (151) in the proximal direction,

comprising a latch (38, 64), provided between barrel and setting member (151), for releasably latching the setting member (124) in a distal position (FIG. 23) in which the cocking spring (172) is cocked,

the cocking spring (172), after disengagement of the latch (38, 64), displacing the setting member (151) a defined distance (FIG. 25: L) out of said distal position (FIG. 23) into a proximal end position (FIG. 25),

comprising external splines (222), provided on the setting member (151), for longitudinal guidance of the setting member (151) in barrel-mounted internal splines (134) substantially complementary to said splines (222),

and comprising external splines (274), provided on the guide member (124), for longitudinal guidance of the guide member (124) in the barrel-mounted internal splines (134).

37. The injection device according to claim 36, wherein the length of the barrel-mounted internal splines (134) corresponds at least to the aforesaid predefined distance (L).

38. The injection device according to claim 36 or 37, wherein in the aforesaid distal position (FIG. 22), the external splines (222) of the setting member (151) are not in engagement with the barrel-mounted internal splines (134).

39. The injection device according to one or more of claims 36 through 38, wherein in the aforesaid distal position (FIG. 22), the external splines (274) of the guide member (124) are in engagement with the barrel-mounted internal splines (134).

40. The injection device according to one or more of claims 36 through 39, wherein in the aforesaid proximal end position (FIG. 25), the external splines (222) of the setting member (151) are in engagement with the barrel-mounted internal splines (134).

41. The injection device according to one or more of claims 36 through 40, wherein in the aforesaid proximal end position (FIG. 25), the external splines (274) of the guide member (124) are in engagement with only a part of their length with the barrel-mounted internal splines (134) (FIG. 25: K5).

42. The injection device according to one or more of claims 36 through 41, wherein a disengageable stop (104) is provided which, after it is disengaged, makes possible a displacement of the guide member (124) into a position (FIG. 27) in which its splines (274) are not in engagement with the barrel-mounted internal splines (134).

43. The injection device according to one or more of Claims 36 through 42, wherein the setting member (151) and the guide member (124) are connected rotatably with respect to one another, but axially substantially nondisplaceably relative to one another.

44. An injection device comprising a container (80) for reception of a cartridge (52) which contains an injection fluid (53) and on whose proximal end an injection needle (76) can be mounted,

comprising a barrel (50, 48, 46, 36) in which said container (80) is displaceable between a proximal end position and a distal position,

comprising a plunger (108), arranged in the barrel and serving to expel injection fluid (53) out of the cartridge (52), which plunger during an injection is guided in a guide member (124) axially displaceably but nonrotatably relative to the barrel, and which has an external thread (159) that is guided in an internal thread (152) of a setting member (151) serving to set the injection dose,

and comprising an apparatus for modifying an axial spacing (Y) in the region between the setting member (151) and the container (80) for purposes of dose setting.

45. The injection device according to claim 44, wherein during an injection, the axial spacing (Y) increased upon dose setting is reduced, and in

particular is reduced to zero.

46. An injection device comprising a container (80) for reception of a cartridge (52) which contains an injection fluid (53) and on whose proximal end an injection needle (76) can be mounted,

comprising a plunger (108), arranged in the barrel and serving to expel injection fluid (53) out of the cartridge (52), which plunger has an external thread (159) that is guided in an internal thread (152) of a setting member (151) serving to set the injection dose,

and which is guided axially displaceably in a guide member (124),

comprising a drive connection (232, 234, 266, 268, 270, 272) which is provided between the guide member (124) and the container (80) and which comprises an apparatus (118, 242; 232, 234) that limits, in at least one rotation direction, the torque transferable from the container (80) to the guide member (124).

47. The injection device according to claim 46, wherein the apparatus for limiting the torque comprises a slip coupling (232, 234).

48. The injection device according to claim 46 or 47, wherein the guide member (124) comprises a coupling (K5) for nonrotatable connection to the barrel, and said coupling (K5) can be disengaged so that a torque can be transferred from the container (80) to the guide member (124) and in order thereby to rotate the latter relative to the barrel.

49. The injection device according to one or more of the foregoing claims, wherein at least one spring member (228), which biases the cartridge (52) in the proximal direction, is provided in the container (80, 116).

50. The injection device according to claim 49, wherein the spring member (228) is configured integrally with a member (116) which can be connected to the container (80) in the manner of a cover.

51. An injection device comprising a barrel (36, 46, 48) wherein a dose-setting apparatus (FIG. 15), for setting a fluid quantity to be injected, is arranged displaceably between a distal end position (FIG. 3) and a proximal end position (FIG. 25),

said dose-setting apparatus having associated therewith a setting member (32) for dose setting,

and the dose-setting apparatus being, at least in its proximal end position (FIG. 25), out of engagement with said setting member (32).

52. An injection device, in particular according to claim 51, wherein a dose-setting apparatus (FIG. 15), for setting a fluid quantity to be injected, is arranged displaceably between a distal end position (FIG. 3) and a proximal end position (FIG. 25),

said dose-setting apparatus having associated with it a setting member (32) for dose setting,

and the dose-setting apparatus (FIG. 15) being, at least in its distal end position (FIG. 3), out of engagement with said setting member (32).

53. The injection device according to claim 51 or 52, wherein the setting member is configured as a rotary knob (32) that is biased resiliently by a torque (190) in the direction toward a zero dose setting, so that when the rotary knob (32) is out of engagement with the dose-setting apparatus (46), it rotates in response to the action of said torque (190) into an initial position, in particular its zero position.

54. The injection device according to one or more of claims 51 through 53, wherein the setting member (32) has splines (196), and the dose-setting apparatus (FIG. 15) is equipped with an engagement member (198) for said splines (196) which, in the proximal and/or distal end position of the dose-setting apparatus, is out of engagement with said splines (196).

55. An injection device, in particular according to one or more of the foregoing claims, which from its proximal end can be brought into a position from which an injection can be triggered.

56. The injection device according to claim 55, in whose barrel (36, 46, 48) a receptacle (80) for the reception of injection fluid (53) is arranged in longitudinally displaceable fashion,

and the displaceable dose-setting apparatus is displaceable, by means of a force acting on the receptacle (80), into a distal end position (FIG. 3).

57. The injection device according to claim 55 or 56, associated with which is a cocking member (FIG. 2: 56) which comprises a thread (58) for threaded joining to a thread (60) provided on the barrel in order, by the creation of said thread connection, to displace the dose-setting apparatus in the distal direction.

58. The injection device according to claim 57, wherein the contact between the cocking member (56) and the receptacle (80) is configured in such a way that the dose-setting apparatus is displaceable in the distal direction as far as a latching position (FIG. 2, FIG. 3) when a needle (76) is installed, but is not when a needle (76) is not installed.

59. The injection device according to claim 58, wherein a container (52) with injection fluid (53) is arranged in a receptacle (80) which comprises at its proximal end a segment (84) on which a carrier (92) of the injection needle (76) can be detachably mounted,

and said segment (84) comprises an opening (98) which, when an injection needle (76) is installed, is covered at least partially by the support (92) thereof,

and comprising a countermember (56A), provided on the cocking member, which is configured for axial engagement into said opening (98) when an injection needle (76) is not installed,

but is in contact against the carrier (92) of the injection needle (76) when the latter is installed.

60. The injection device according to claim 59, wherein the countermember (56A) provided on the cocking member (56) is configured in the manner of a

hollow cylindrical extension on the inner side of the cocking member (56).

61. The injection device according to one or more of Claims 51 through 60, wherein the dose-setting apparatus (FIG. 15) that is displaceable in the barrel (36, 46, 48) comprises a dose setting member (148, 150) which, in a distal end position region (FIG. 19, FIG. 22), is rotatable relative to the barrel so as to make possible a dose setting by means of that rotation.

62. The injection device according to claim 61, wherein the dose setting member (148, 150) has associated therewith a guide arrangement (134) which, in a position region adjacent to the distal end position region, guides it in the barrel axially and substantially nonrotatably (FIG. 13).

63. The injection device according to claim 61 or 62, wherein a thread (152) of the dose setting member (148, 150) are in engagement with a threaded rod (108), the latter being arranged nonrotatably and axially displaceably relative to the barrel, and being configured for the expulsion of injection fluid (53) during the injection operation.

64. The injection device according to one or more of claims 51 through 63, wherein the dose-setting apparatus (FIG. 15) has associated with it a cocking spring (172) which biases the dose-setting apparatus in the proximal direction, and a latch (38, 64) is provided in order to latch the dose-setting apparatus in the barrel after displacement in the distal direction, i.e. against the force of the cocking spring (172).

65. The injection device according to claim 64, wherein the dose-setting apparatus (FIG. 15) has a resilient latching member (64) associated with which, on the barrel (36), is an opening (38) into which said resilient latching member (64) can snap.

66. The injection device according to claim 65, wherein the opening (38) provided on the barrel is configured such that when the resilient latching member (64) is in its snapped-in state, it allows an axial displacement of the latter into a first distal position (FIG. 19) in which the dose-setting apparatus is out of engagement with the setting member (32).

67. The injection device according to claim 66, wherein the opening (38) provided on the barrel (36) is configured such that the resilient latching member (64), in its snapped-in state, is displaceable into a second distal position (FIG. 22), different from the first distal position (FIG. 19), in which the dose-setting apparatus is in engagement with the setting member (32) and can be actuated by the latter.

68. An injection device comprising an indicating apparatus for the injection dose that is set, in particular according to one or more of the foregoing claims,

comprising a scale (69') which comprises in a first row (71) a first series of indicating digits and in a second row (73) a second series of indicating digits,

and comprising a double magnifier (42), serving to indicate the dose, of which the one magnifier (70) is associated with the first row (71), and the other magnifier (72) with the second row (73), of indicating digits.

69. The injection device according to claim 68, wherein the first series comprises digits (e.g. even numbers) whose values lie between the values of the digits (e.g. odd numbers) of the second series.

70. The injection device according to claim 68 or 69, wherein the rows (71, 73) are configured such that upon setting of the dose, each indicated value in the one magnifier (70) is followed by an indicated value in the other magnifier (72).

MODIFIED CLAIMS
received at the International Office June 30, 2000; new claims 71-108 added; all other claims unchanged (7 pages)

71. An injection device comprising a housing (50, 48, 46, 36) with a container (80), arranged in said housing, for reception of a cartridge (52) which contains an injection fluid (53) and on whose proximal end an injection needle (76) can be mounted,

comprising a plunger (108), arranged in the housing and serving to expel injection fluid out of the cartridge (52), which is guided in a guide member (124) axially displaceably but nonrotatably relative to the guide member,

and which has an external thread (159) that is guided in an internal thread (152) of a setting member (151) provided for dose setting,

comprising a first coupling arrangement (K4) for nonrotatable but axially displaceable coupling of the setting member (151) to the housing, said coupling arrangement (K4) being deactivated during dose setting,

comprising a second coupling arrangement (K5) for nonrotatable but axially displaceable coupling of the guide member (124) to the housing,

and comprising an apparatus (50) for activating the first coupling arrangement (K4) and for disabling the second coupling arrangement (K5), in order to make the guide member (124) rotatable relative to the housing and the setting member (151) nonrotatable relative to the housing, and to make possible an axial movement of the plunger (108) by rotation of the guide member (124).

72. The injection device according to claim 71, wherein there is provided between guide member (124) and setting member (151) a connection (278, 282) that joins said two parts to one another rotatably but substantially axially nondisplaceably.

73. The injection device according to claim 71 or 72, wherein both the guide member (124) and the setting member (151) have external splines (274 and 222, respectively),

and said external spline sets have associated therewith internal splines (134) in the housing (36), into which said external spline sets (222, 274) can engage, individually or together, by means of a longitudinal displacement of guide member (124) and setting member (151) occurring relative to the housing (36).

74. The injection device according to claim 73, wherein the setting member (151) is equipped with a latching member (64), by means of which the setting member (151) can be releasably latched in a predefined axial position relative to the housing (36) in which its external splines (222) are not in engagement

with the internal splines (134) in the housing (36).

75. The injection device according to claim 74, wherein the setting member (151) is rotatable relative to the latching member (64) provided on it.

76. The injection device according to one of claims 73 through 75, wherein a latching member (64) is provided by means of which the guide member (124) can be releasably latched in a predefined axial position relative to the housing (36) and in which its external splines (274) are in engagement with the internal splines (134) in the housing (36).

77. The injection device according to one of claims 70 through 76, wherein the setting member (151) is biased by a spring (172) in the proximal direction.

78. The injection device according to claim 71, wherein there is provided, between the container (80) for the cartridge (52) and the guide member (124), a drive connection (266, 268, 270, 272) which makes possible the transfer of a torque from the container (80) to the guide member (124).

79. The injection device according to claim 78, wherein the drive connection (266, 268, 270, 272) comprises at least one apparatus (118, 242; 232, 234) that limits, in at least one rotation direction, the torque transferable from the container (80) to the guide member (124).

80. The injection device according to claim 79, wherein the apparatus for limiting the torque comprises a slip coupling (232, 234).

81. The injection device according to claim 80, wherein the slip coupling (232, 234) is effective for the rotation direction (FIG. 32: 321) in which a disengageable connection (115, 118) closing the container (80) is being closed.

82. The injection device according to one of claims 70 through 81, wherein a lock (111, 112) is provided for locking rotation of the container (80) relative to the housing receiving it, said lock being disengaged upon replacement of a cartridge (52).

83. The injection device according to claim 82, wherein the outer side of the container (80) is axially guided (FIG. 5: 112) in the inner side of a housing part (48), and this axial guidance (111, 112) is deactivated when the housing is opened in order to replace a cartridge (52).

84. The injection device according to one of claims 70 through 83, wherein the container (80) can be closed and opened by means of a disengageable connection (115, 118) so that a cartridge (52) can be introduced or removed.

85. The injection device according to claim 84, wherein the disengageable connection (115, 118) comprises an apparatus (118, 242) for generating an elevated breakaway torque in order temporarily to necessitate an elevated torque for disengaging it.

86. The injection device according to claim 84 or 85, wherein the disengageable connection (115, 118) comprises an element (116) that is connected via a drive connection (266, 268, 270, 272) to the guide member (124), said drive connection making possible an axial relative movement between said element (116) and the guide member (124).

87. The injection device according to claim 86, wherein during dose setting, the axial spacing (FIG. 23: Y) between the guide member (124) and said element (116) is modified.

88. The injection device according to one of claims 70 through 87, wherein the plunger (108) has associated with it a latching apparatus (FIG. 29: K2) in order to latch the latter disengageably in a defined position (FIG. 29) relative to the setting member (151).

89. The injection device according to claim 88, wherein upon replacement of a cartridge (52), latching is activated by means of the position-dependent latching apparatus (FIG. 29: K2) in order to immobilize the plunger (108) in the defined position (FIG. 29) after opening and before closing of the container (80).

90. The injection device according to one of claims 70 through 89, wherein at least one working action necessary for replacement of a cartridge (52) is used to influence the position of the plunger (108) relative to the setting member (151).

91. The injection device according to one of claims 70 through 90, comprising a spring (172) which is cocked before an injection and which, after an injection is triggered, causes an insertion of the injection needle (76) and an expulsion of fluid (53) from the cartridge (52) through the injection needle (76).

92. The injection device according to claim 91, wherein the spring (172) is cocked from the proximal end of the injection device (30).

93. The injection device according to claim 92, wherein the housing (50) comprises a thread (60) in its proximal region; and a cocking member (56) is provided which is equipped with a thread (58) complementary to said thread (60) and is configured to displace the container (80), configured for reception of a cartridge (52), in the housing in the distal direction (315).

94. The injection device according to claim 93, wherein a latching member (64) is provided which, after a defined displacement travel in the distal direction (315), snaps into a latch opening (38),
and said defined displacement travel can be achieved only if an injection needle (76) is installed.

95. The injection device according to one of claims 70 through 94, wherein the setting member (151) can be coupled via a travel-dependent coupling (K1) to a setting element (32) for setting the injection dose.

96. The injection device according to claim 95, wherein the travel-dependent coupling (K1) is out of engagement during cartridge replacement (FIGS. 26 through 32).

97. The injection device according to one of claims 70 through 96,

comprising a latching apparatus (38, 64), provided between housing and setting member (151), for releasably latching the guide member (124) and/or the setting member (124) in a distal position (FIG. 23) in which the cocking spring (172) is cocked,

the cocking spring (172), after disengagement of the latching apparatus (38, 64), displacing the setting member (151) a defined distance (FIG. 25: L) out of said distal position (FIG. 23) into a proximal end position (FIG. 25),

comprising external splines (222), provided on the setting member (151), for longitudinal guidance of the setting member (151) in housing-mounted internal splines (134) substantially complementary to said splines (222),

and comprising external splines (274), provided on the guide member (124), for longitudinal guidance of the guide member (124) in said housing-mounted internal splines (134).

98. The injection device according to claim 97, wherein the length of the internal splines (134) corresponds at least to the aforesaid defined distance (L).

99. The injection device according to claim 97 or 98, wherein in the aforesaid distal position (FIG. 22), the external splines (222) of the setting member (151) are not in engagement with the housing-mounted internal splines (134).

100. The injection device according to one of claims 97 through 99, wherein in the aforesaid distal position (FIG. 22), the external splines (274) of the guide member (124) are in engagement with the housing-mounted internal splines (134).

101. The injection device according to one of claims 97 through 100, wherein in the aforesaid proximal end position (FIG. 25), the external splines (222) of the setting member (151) are in engagement with the housing-mounted internal splines (134).

102. The injection device according to one of claims 97 through 101, wherein in the aforesaid proximal end position (FIG. 25), the external splines (274) of the guide member (124) are in engagement with only a part of their length with the housing-mounted internal splines (134) (FIG. 25: K5).

103. The injection device according to one of claims 97 through 102, wherein a disengageable abutment (104) is provided which, after it is disengaged, makes possible a displacement of the guide member (124) into a position (FIG. 27) in which its splines (274) are not in engagement with the housing-mounted

internal splines (134), in order to make possible, by rotation of the guide member (124), a movement of the plunger (108) relative to the housing.

104. The injection device according to one of claims 97 through 103, wherein the setting member (151) and the guide member (124) are joined rotatably with respect to one another, but axially substantially nondisplaceably relative to one another.

105. An injection device comprising a container (80) for reception of a cartridge (52) which contains an injection fluid (53) and on whose proximal end an injection needle (76) can be mounted,

comprising a housing (50, 48, 46, 36) in which said container (80) is displaceable between a proximal and a distal position,

comprising a plunger (108), arranged in the housing and serving to expel injection fluid (53) out of the cartridge (52), which has an external thread (159) that is guided in an internal thread (152) of a setting member (151) serving to set the injection dose,

and which is guided axially displaceably in a guide member (124),

and comprising a drive connection (232, 234, 266, 268, 270, 272)

- which is provided between the guide member (124) and the container (80)

- and which comprises an apparatus (118, 242; 232, 234) that limits, in at least one rotation direction, a torque transferable from the container (80) to the guide member (124),

in order to make possible, by the transfer of a limited torque from the container (80) to the guide member (124) after a cartridge replacement, a displacement of the plunger (108) in the proximal direction into contact against a piston (106) provided in the cartridge (52).

106. The injection device according to claim 105, wherein the apparatus for limiting the torque comprises a slip coupling (232, 234).

107. The injection device according to one of claims 70 through 106, wherein at least one spring member (228), which biases the cartridge (52) in the proximal direction, is provided in the container (80, 116).

108. The injection device according to claim 107, wherein the spring member (228) is configured integrally with a member (116) which can be joined in the manner of a cover to the container (80).

ABSTRACT

An injection device has a container (80) for reception of a cartridge (52) which contains an injection fluid (53) and on whose proximal end an injection needle (76) can be mounted. This container is displaceable in a housing (50, 48, 46, 36) between a proximal end position and a distal end position. Arranged in the housing is a plunger (108), serving to expel injection fluid (53) out of the cartridge (52), which during an injection is guided in a guide member (124) axially displaceably but nonrotatably relative to the housing, and has an external thread (159) that is guided in an internal thread (152) of a setting member (151) which serves to set the injection dose. Provided between the container (80) and the plunger (108) is a frictionally engaging coupling (162, 250) which, in the manner of a slip coupling, serves to transfer at least a portion of an axial movement of the plunger (108) to the container (80).

STATEMENT CITED IN ARTICLE 19

The additional claims 71 through 108 refer to replacement of the cartridge (52) comprising the injection fluid.

These claims are based, in the present Application, principally on page 21, starting at the penultimate paragraph, and pages 22, 23, 25, and 26. Cartridge replacement is depicted in Figures 26 through 33.